STRATEGIES TO MAXIMIZE



Association of American Cancer Institutes

Medical Arts Building 3708 Fifth Avenue, Suite 503 Pittsburgh, PA 15213

Phone: 412-647-6111

www.aaci-cancer.org

11TH ANNUAL MEETING - JULY 9-11, 2019



LOEWS CHICAGO O'HARE HOTEL ROSEMONT, ILLINOIS

AACI CRI 2019 Steering Committee

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

Theresa L. Werner, MD – Chair-Elect Huntsman Cancer Institute, University of Utah

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

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

Stefan C. Grant, MD, JD, MBA Wake Forest Baptist Comprehensive Cancer Center

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

Collette M. Houston Memorial Sloan Kettering Cancer Center

> Wireless Internet, Presentations, and Social Media

Wireless Network: AACI CRI Wi-Fi Password: 2019cri

To access CRI annual meeting presentations please download the CrowdCompass AttendeeHub app.

Twitter: @AACI_Cancer Facebook: AACICancer Hashtag: #CRI2019 Ashley Baker Lee, CCRP City of Hope Comprehensive Cancer Center

Tara L. Lin, MD The University of Kansas Cancer Center

Kristie Moffett, MHA Moffitt Cancer Center

Melissa A. Nashawati, MPA Mays Cancer Center, UT Health San Antonio

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

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

Looking for presentations, exhibitors, or other attendees? Find everything you need in the meeting event app! STEP 1: Download the "CrowdCompass AttendeeHub" app. STEP 2:

Find the "AACI CRI" event in the app and download to your device.

STEP 3: Log in with your name and email from registration. You will receive a 4-digit verification code.

STEP 4:

Verify your account by entering the code you received. When prompted, click "verify" to proceed to the app home page.

AACI CRI Welcome

With more than a decade of consistent growth, the Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) program has expanded from an initiative into a permanent fixture among cancer center clinical trials professionals. To recognize CRI's pioneering efforts to develop and disseminate best practices for cancer clinical trials, AACI renamed the program in 2018. CRI's forward momentum also drives the programming of the 11th Annual AACI CRI Meeting, "Strategies to Maximize Innovation and Advance Cancer Clinical Research."

The CRI annual meeting program aligns with AACI's strategic goal of stimulating cancer center interactions to maximize resources by creating opportunities for peer-to-peer networking and collaboration. CRI participants fill a variety of leadership roles and possess a comprehensive understanding of the clinical trials system.

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 to clinical trials
- 5. Develop outcomes to drive change and advance cancer center clinical research programs
- 6. Develop a training curriculum for new principal investigators and clinical trials office administrative directors
- 7. Increase engagement with industry and other stakeholders to support CRI

AACI CRI Meeting Objectives

- 1. Practice mind-body coordination to enhance self-awareness, build resiliency, and reduce burnout
- 2. Learn how to effectively run multicenter clinical trials
- 3. Learn and apply conflict resolution skills to help team members reach their full potential
- 4. Discuss approaches for matching patients who have genetic mutations with clinical trials
- 5. Discuss key pre- and post-activation steps in clinical trials, such as reviewing trial feasibility and developing consistent policies for closing trials
- 6. Learn how cancer center leaders have used clinical trial data to analyze downstream revenue and demonstrate the value of the clinical trials office (CTO) to hospital and institutional administrators
- 7. Explore innovative solutions to common challenges that arise during trial start-up
- 8. Discuss strategies for enrolling patients from diverse backgrounds to clinical trials and the challenges that prevent cancer centers from reaching their recruitment goals
- 9. Learn to prepare a successful National Cancer Institute (NCI) Cancer Center Support Grant (CCSG) application

Who Attends This Meeting?

- Individuals from AACI member cancer centers, including:
 - CTO administrative directors, medical directors, managers, and supervisors
 - Deputy/associate directors of clinical research administration
 - Cancer center administrators
 - Research regulatory management and staff
 - Clinical research finance directors, managers, and supervisors
 - Biostatisticians and informatics specialists
- Individuals from U.S. Department of Health and Human Services agencies and offices, including the NCI and the U.S. Food and Drug Administration
- AACI sustaining members
- AACI Corporate Roundtable members
- Representatives from industry, including drug development companies, clinical research organizations, and consultants
- IT companies that support cancer center clinical research management
- Like-minded organizations promoting patient access to clinical trials

MEETING PROGRAM

11th Annual AACI Clinical Research Innovation Meeting

Tuesday, July 9 – Thursday, July 11, Loews Chicago O'Hare Hotel

Tuesday, July 9

11:00 AM Registration Opens - Artist Foyer

- 1:00 PM Exhibits Open Artist Foyer
- **1:00 PM** Welcome and Opening Remarks Cassatt Ballroom

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

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

Carrie Lee, MD, MPH

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

1:30 PM How to Capitalize on Conducting Multicenter Trials Cassatt Ballroom

Attendees will learn how to set expectations to ensure that multicenter trials are run effectively. Topics for discussion include how to operationalize investigator-initiated trials and managing multiple sites under a single IRB review.

Moderator: Melissa A. Nashawati, MPA

Mays Cancer Center, UT Health San Antonio

Moshe A. Kelsen, MBA

Herbert Irving Comprehensive Cancer Center Columbia University Irving Medical Center

Marie J. Malikowski, MHA, CCRP

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

2:30 PM Networking Break

3:00 PM Managing Teams, Resolving Conflicts, and Inspiring Performance - Cassatt Ballroom

Teamwork is an essential element of any workplace, but a team's effectiveness can vary based on each member's strengths and weaknesses. In this session, attendees will learn conflict resolution skills and tactics to help all team members reach their full potential. Human resources experts will provide real-world examples and strategies that can be applied to a variety of work environments, including clinical trials offices.

Moderator/Presenter: Alex Zafirovski, MBA

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

Ahlam Al-Kodmany, PhD

University of Illinois Cancer Center

Casey Cook The University of Chicago

4:00 PM Using Clinical Trial Matching to Enhance Enrollment Cassatt Ballroom

Panelists will discuss strategies for matching patients who have genetic mutations with clinical trials. They will also explore the benefits of clinical trial navigators and navigation services.

Moderator: Carrie Lee, MD, MPH

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

Tufia C. Haddad, MD

Mayo Clinic Cancer Center

Bobbie Rimel, MD

Samuel Oschin Comprehensive Cancer Institute Cedars-Sinai Medical Center

Jeffrey Thompson, PhD

The University of Kansas Cancer Center

5:00 PM Poster Session - Avedon Ballroom

	6:00 -	Welcome	Reception	- Artist Foyer
--	--------	---------	-----------	----------------

7:00 PM Sponsored by Forte

Wednesday, July 10

7:00 AM Exhibits Open - Artist Foyer

7:00 AM Breakfast - Louvre Ballroom, Museum Wing

8:00 AM Welcome - Cassatt Ballroom

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 Keynote Presentation: Strategies for Self-Preservation Cassatt Ballroom

Self-care has become a buzzword in recent years, and for good reason: many struggle with stress in their personal and professional lives, often leading to burnout. Raquel Forsgren, founder of Front-Line Resilience Health and Living Yoga Therapy in Chicago, will provide tools for managing stress, reducing fatigue, defining clear boundaries, and building resiliency to counteract "compassion fatigue." Drawing from years of experience in both the oncology pharmaceutical field and yoga therapy, Forsgren will incorporate mind-body activities into her presentation to show how participants can better control their daily lives by learning how to relax, keeping an open mind, and developing self-awareness.

Raquel Forsgren

Front-Line Resilience Health and Living Yoga Therapy

9:30 AM Trial Pre-Activation: Managing Resources at the Disease Team and Institutional Levels - Cassatt Ballroom

Participants will learn the nuts and bolts of the trial pre-activation process, such as reviewing feasibility for opening the right trials, managing CTO resources, and establishing protocol activation and review cores.

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

Andrea Andrews, CCRP Stephenson Cancer Center, University of Oklahoma

Sara Hanley, MSW

Memorial Sloan Kettering Cancer Center

10:30 AM Coffee Break Sponsored by Huron

10:45 AM Concurrent Poster Sessions - Avedon Ballroom

Concurrent poster sessions provide opportunities for abstract authors to inform meeting attendees about CTO challenges and solutions implemented at AACI cancer centers. Three posters will be featured in each session.

Posters are organized into the following categories:

Avedon D	Avedon C	Avedon B
Clinical Research Operations	Investigator-Initiated Trials	Trial Recruitment and
Finance/CCSG/PRMS	Regulatory	Disparities Research
	Training and Quality Assurance	Trial Start-up/Closure

11:45 AM Lunch - Louvre Ballroom, Museum Wing

12:45 PM CRI Progress Report - Cassatt Ballroom

Members will report on the status of CRI's Regulatory File Management Working Group and the CRI Shared Investigator Platform (SIP) Task Force. Discussion will include highlights of the past year and planned outcomes for the coming year.

Kyusun Cha, CCRC

UCSF Helen Diller Family Comprehensive Cancer Center

Nicholas Cimaglia

Memorial Sloan Kettering Cancer Center

1:15 PM Trial Post-Activation: Managing Resources at the Disease Team and Institutional Levels - Cassatt Ballroom

Panelists will discuss the key components of the post-activation stage of clinical trials. Topics will include ways to effectively manage trials and resources, determining the appropriate amount of auditing for your CTO, and developing consistent policies for closing trials.

Moderator: Tricia Adrales Bentz, MHA, CCRP

Hollings Cancer Center, Medical University of South Carolina

Alexandra Annis, CCRP

UAMS Winthrop P. Rockefeller Cancer Institute

Amanda Hammond

City of Hope Comprehensive Cancer Center

2:00 PM Compassionate Use Program: Making the Business Case to Your Health System - Cassatt Ballroom

The need for a compassionate use program is growing at many centers. During this session, the panel will discuss the rationale, policies, and procedures for implementing a compassionate use program. Panelists will also discuss the operations and infrastructure necessary to support a program, and address strategies for approaching institutional leadership and making the business case for the program.

Moderator: Theresa Werner, MD

Huntsman Cancer Institute, University of Utah

Misty Gravelin, MPH University of Michigan

Blair Holbein, PhD

Simmons Comprehensive Cancer Center, UT Southwestern Medical Center

Carolyn Passaglia, CCRP

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

Emily Wilson

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

3:00 PM	Dessert Break Sponsored by Essex Management
---------	---

3:15 PM 2019 CRI Abstract Presentations - Cassatt Ballroom

Abstracts received from AACI cancer center members illuminate clinical research challenges and solutions for accelerating cancer drug development. The CRI steering committee and education committee have selected three abstracts for presentation at this year's meeting.

Moderator: Carrie Lee, MD, MPH

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

FIRST PLACE: Electronic Informed Consent (eIC) Platform for Clinical Trials: An Operational Model and Suite of Tools for Consent Authoring, Obtaining Informed Consent, and Managing Consent Documents

J. Lengfellner, M. Buckley, M. Koch, H. Pacheco, J. Levine, C. Hoidra, D. Damron, C. Houston, R. Cambria, A. Rodavitch, P. Sabbatini, E. Cottington Memorial Sloan Kettering Cancer Center

SECOND PLACE: Implementation of an Oncology Clinical Research Merit-Based Recognition Program for Physicians T. Adrales Bentz, C. Britten, D. Berrier, D. Marshall Hollings Cancer Center, Medical University of South Carolina

THIRD PLACE: MNCCTN: Challenges to Opening a State-Wide Network and the Pathway to Success - A 2-Year Perspective M.L. Rahne, R. Leed, C. Stibbe, J. Alkire Masonic Cancer Center, University of Minnesota

4:15 PM Concurrent Poster Sessions - Avedon Ballroom

Concurrent poster sessions provide opportunities for abstract authors to inform meeting attendees about CTO challenges and solutions implemented at AACI cancer centers. Three posters will be featured in each session.

Posters are organized into the following categories:

Avedon D	Avedon C	Avedon B
Clinical Research Operations	Investigator-Initiated Trials	Trial Recruitment and
Finance/CCSG/PRMS	Regulatory	Disparities Research
	Training and Quality Assurance	Trial Start-up/Closure

- 5:15 PM Vendor Presentation: Complion Avedon Ballroom A eRegulatory: Advancing Clinical Research Through Consistency and Standardization
- **6:30 PM Dine Arounds** Various local restaurants Sign-up is available at registration until 12:45 PM. Availability is limited.
- 8:00 Hospitality Ice Bar, Lobby Level 10:00 PM Sponsored by Florence

Thursday, July 11

7:00 AM Breakfast - Louvre Ballroom, Museum Wing

8:00 AM Welcome - Cassatt Ballroom

Carrie Lee, MD, MPH

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

Theresa Werner, MD

Huntsman Cancer Institute, University of Utah

8:15 AM Clinical Trial Finance Management: Matching CTO Resources with Innovative Therapies - Cassatt Ballroom

Creative strategies for generating clinical trial revenue are critical to sustaining an oncology clinical research program and demonstrating the value of clinical research is key to seeking university or health system support of the CTO. Finance experts from AACI cancer centers will offer current solutions to common challenges with creating trial budgets for immuno-oncology trials, collecting trial data to demonstrate downstream revenue generated from trials, and ensuring trial budget costs match with efforts for conducting research.

Moderator/Presenter: Collette Houston

Memorial Sloan Kettering Cancer Center

John Musser Moffitt Cancer Center

Michael Sainz Dartmouth-Hitchcock Norris Cotton Cancer Center

9:15 AM Getting to Know Your Patients: Enrolling Diverse Populations to Clinical Trials - Cassatt Ballroom

Panelists will discuss innovative ways to enroll patients from diverse backgrounds to clinical trials. Specifically, panelists will focus on resources to increase recruitment and engagement of patients from minority groups, improved screening using community data, and common challenges that prevent cancer centers from reaching adequate representation of minorities.

Moderator: Tara Lin, MD The University of Kansas Cancer Center

Patricia Chalela, DrPH Mays Cancer Center, UT Health San Antonio

Chanita Hughes Halbert, PhD Medical College of South Carolina

Robert Winn, MD University of Illinois Cancer Center

10:15 AM Coffee Break Sponsored by Huron

AACI CRI Meeting 2019 Abstracts

10:30 AM Preparing for the NCI Cancer Center Support Grant (CCSG) - Cassatt Ballroom

Presenters will examine updates to the CCSG submission guidelines as they pertain to CTO leadership. They will also highlight revisions to the funding opportunity agreement (FOA) that will take effect in January 2020, including new catchment area definitions and adjustments to the community outreach and engagement (COE) and protocol review and monitoring sections. In addition, presenters will discuss modifications to the clinical trials reporting program (CTRP).

Moderator: Theresa Cummings

University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center

Henry Ciolino, PhD

National Cancer Institute

Gisele Sarosy, MD National Cancer Institute

11:30 AM Closing Remarks

Janie Hofacker, RN, BSN, MS

Association of American Cancer Institutes

11:45 AM Adjourn

FIRST PLACE: Electronic Informed Consent (eIC) Platform for Clinical Trials: An Operational Model and Suite of Tools for Consent Authoring, Obtaining Informed Consent, and Managing Consent Documents J. Lengfellner, M. Buckley, M. Koch, H. Pacheco, J. Levine, C. Hoidra, D. Damron, C. Houston, R. Cambria, A. Rodavitch, P. Sabbatini, E. Cottington Memorial Sloan Kettering Cancer Center

SECOND PLACE: Implementation of an Oncology Clinical Research Merit-Based Recognition Program for Physicians T. Adrales Bentz, C. Britten, D. Berrier, D. Marshall Hollings Cancer Center, Medical University of South Carolina

THIRD PLACE: MNCCTN: Challenges to Opening a State-Wide Network and the Pathway to Success - A 2-Year Perspective M.L. Rahne, R. Leed, C. Stibbe, J. Alkire Masonic Cancer Center, University of Minnesota

Additional abstracts (by category and alphabetical order by AACI cancer center):

Clinical Research Operations

- Multifunctional Staff Focus Groups as a Tool to Improve Employee Engagement of Clinical Trials Office Staff
 Lange, S. Bigelow, C. Brown, P. Dykema, D. Erickson, L. Jakovski Barbara Ann Karmanos Cancer Institute, Wayne State University
- 2.* THAW The Holistic Approach for Working in Cellular and Gene Therapy Clinical Trials
 J. Gould, K. Shrestha, R. McCray, F. Brogan, D. Otap, M. Kelsen, M. Mapara, R. Reshef, A. Lassman
 Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center
- 3.* Implementation of an Oncology Clinical Research Merit-Based Recognition Program for Physicians T. Adrales Bentz, C. Britten, D. Berrier, D. Marshall Hollings Cancer Center, Medical University of South Carolina
- 4.* Full Integration of the Gynecology Oncology Research Operations Under the IU Simon Cancer Center Clinical Trials Office M. Contreraz, S. Edwards, L. Vaughn, K. Miller Indiana University Melvin and Bren Simon Cancer Center
- 5.* Developing an Automated Deviation Reporting and Electronic PI Attestation Process

 L. Rohn, J. Nichols, A. Semla, S. Asche, J. Leiriao Indiana University Melvin and Bren Simon Cancer Center

2019 Abstracts

- 6.•* Development of a Systematic Review of Molecular Testing Increases Precision Medicine Based Clinical Trial Screening and Awareness M. Lasowski, B. George, B. Oleson, J. Thomas Medical College of Wisconsin Cancer Center
- 7.* Electronic Informed Consent (eIC) Platform for Clinical Trials: An Operational Model and Suite of Tools for Consent Authoring, Obtaining Informed Consent, and Managing Consent Documents J. Lengfellner, M. Buckley, M. Koch, H. Pacheco, J. Levine, C. Hoidra, D. Damron, C. Houston, R. Cambria, A. Rodavitch, P. Sabbatini, E. Cottington Memorial Sloan Kettering Cancer Center

8.* Reducing Overhead During Study Startup With System Integrations N. VanKuren¹, R. Jones², A. Garcia² ¹Sidney Kimmel Cancer Center at Jefferson Health; ²Florence Healthcare

- 9.* Connecting the Supply Chain D.P. Mudaranthakam¹, J. Thompson¹, J. McIlwain² ¹The University of Kansas Cancer Center; ²Velos
- 10.**Data Analytics on Data Reporting: Building on Current Tools to Transform Available Data Into Useful Tools
 K. Cha, A. Skafel, M. Kock, E. Pon UCSF Helen Diller Family Comprehensive Cancer Center
- 11.* Implementation and Application of the Ontario Protocol Assessment Level Tool at the Helen Diller Family Comprehensive Cancer Center
 M. Kock, C. Aoun, K. Cha, A. Skafel UCSF Helen Diller Family Comprehensive Cancer Center
- 12.* Creating a Clinical Research Network A. Yost, L. Curran, A. Skafel, M. Feng, E. Small UCSF Helen Diller Family Comprehensive Cancer Center
- 13.* Building a Clinical Career Ladder S. Belanger, S. Ladd UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill
- 14.* Deployment of a Cancer Population Science Clinical Research Navigator to Improve Engagement With CPS Investigators A. Anderson, A. Ivey, T. George University of Florida Health Cancer Center
- 15.* A Data Informed Approach to Staffing Using OnCore L. Pettiford, A. Ivey, H. Koranne, W.J. Stokes, T. George University of Florida Health Cancer Center

12

16.* Institutional Perspectives on Cancer Community Activation Timelines S. Stewart¹, W. Tate², L. Hilty²

¹University of Wisconsin Carbone Cancer Center; ²Forte Research Systems

- 17.* A Task-Based Automated Comprehensive Assessment Tool for Clinical Trial-Associated Workload J. Plassmeyer, D. Cleary, C. Muniz, B. Crocker, K. Yee, K. Richter, B. Pappu UPMC Hillman Cancer Center
- 18.* Creating the Standard for Specialized Nurse Training in the Phase I Clinical Trials Setting C. Belmore, J. Bourgeois, J. Warren, C. Lewis, R.D. Harvey, T. Mann Winship Cancer Institute of Emory University
- 19.* Designing a Phase I Clinical Trial Unit: A Multidisciplinary Collaborative Approach
 C. Lewis¹, A. Kim², M. Childress¹, T.K. Owonikoko¹, M.A. Bilen¹, B. El-Rayes¹, J. Bourgeois¹, H. Collins¹, C. Belmore¹, T. Williams¹, J. Warren¹, M. Goodman¹, K. Culver¹, M. Williams¹, E. Barton-Judson¹, S. John¹, R.D. Harvey¹
 ¹Winship Cancer Institute of Emory University; ²Simpler Consulting, an IBM Company

Finance/CCSG/PRMS

- 20. CTO Financial Dashboard A. Bowler, E. Bake, C. Ross Huntsman Cancer Institute, University of Utah
- 21.* What's in a Pre-Review? Establishing a Streamlined Method for Ensuring Quality Submissions to Protocol Review Committees J. Migliacci, A. McKeown, A. Motta, D. Diaz-Leyton, C. Kolenut, X. Lekperic, K. Napolitano, C. Ryan, S. Hanley, A. Rodavitch Memorial Sloan Kettering Cancer Center
- 22.* Re-Envisioning Memorial Sloan Kettering's Data and Safety Monitoring Committee X. Lekperic, K. Napolitano, S. Hanley, C. Kolenut, A. Rodavitch, C. Houston, E.M. O'Reilly Memorial Sloan Kettering Cancer Center
- 23.•*Enhancing the Capture of Oncology Study Activity via Scientific Review and IRB Collaboration A. Anderson, T. George, A. Ivey University of Florida Health Cancer Center
- 24.* Establishment of a Zero Tolerance Policy to Eliminate Non-Performing Studies T. George, A. Ivey, A. Anderson, T. Guinn University of Florida Health Cancer Center

Investigator-Initiated Trials

25.* Investigator-Initiated Trial Activation: Increasing Collaboration With a Protocol Navigator K. Thorne Huntsman Cancer Institute, University of Utah

2019 Abstracts

- 26.* Multicenter Investigator-Initiated Trial Prioritization L. Sego, A. Bauchle, M. Darling, K. Miller, P. Loehrer, S. Farag, S. Edwards Indiana University Melvin and Bren Simon Cancer Center
- 27.* Implementation of a Concept Development Program for Investigator-Initiated Trials
 A. Ivey, A. Daniels, T. George University of Florida Health Cancer Center

Regulatory

14

- 28.* SOP Implementation for Managing CIRB Studies in Data Analysis Only Status S. Edwards, B. Johnson, I. SerVaas Indiana University Melvin and Bren Simon Cancer Center
- 29.* How to Implement a Master Delegation of Authority Process Across a Clinical Trials Office L. Rohn, T. Detty, A. Semla, S. Asche, K. Ackerman Indiana University Melvin and Bren Simon Cancer Center
- 30.* Driving Innovation Through Regulatory and Product Development Magic
 R. Ellis, S. Oliver, L. Shrestha, A. Yadav, O. Hauke Memorial Sloan Kettering Cancer Center
- 31.* GOING LIVE With an e-Regulatory System: Lessons Learned in Managing the Change Process During an e-Regulatory Rollout at a Comprehensive Cancer Center A. Drawz¹, K. Akula¹, C. Passaglia¹, M. Hurley² ¹Robert H. Lurie Comprehensive Cancer Center of Northwestern University; ²Complion, Inc.
- 32. Overcoming the Burden of Paper Regulatory Binders Through eReg and eSignature Implementation A. Green, M. Brown, K. Linsenmeyer, J. Gonzalez The Ohio State University Comprehensive Cancer Center James Cancer Hospital & Solove Research Institute

Training and Quality Assurance

- 33.* The Elephant in the Room Onboarding of New Staff in an Evolving Research Landscape Plagued by Turnover
 D. Farhat, J. Ventimiglia, E. Horvat, L. Casetta, J. Mancini Barbara Ann Karmanos Cancer Institute, Wayne State University
- 34.* Interactive Web-Based Imaging Response Assessment Training Application for Cancer Clinical Trials
 T. Urban, E. Ziegler, B. Somarouthu, D. Rukas, M. Leary, E. Correa, G. Basinsky, A. Van den Abbeele, G. Harris Dana-Farber Cancer Institute, Harvard Medical School
- **35.* Risk-Based Monitoring as a Mechanism to Inform DSMC Practices T. Negri, D. Otap, M. Kelsen, F. Brogan, L. Blumberg, S. Kelly, J. Wang, M. Galazyn, J. Jurcic** *Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center*

- 36.* How to Be a Principal Investigator: A Practical Training Program for Investigators
 R. Kingsford, D. Pitt, S. Low, L. Weaver, J. Moehle, A. Cohen, T. Werner Huntsman Cancer Institute, University of Utah
- 37.* Increasing Minority Oncology REpresentation (MORE) in Clinical Trials S. Milescu, L. Vaughn, A. Al-Hader, S. Rawl, M. Contreraz, K. Miller Indiana University Melvin and Bren Simon Cancer Center
- 38.* The Case for a Designated Clinical Research Educator M. Gray, R. Selle, B. Oleson, J. Thomas Medical College of Wisconsin Cancer Center
- 39.**Developing a Standardized Library of Informed Consent Language to Ensure Consistency and Quality Across Clinical Trials at a Large Academic Medical Center
 S. Briggs, C. Hoidra, D. Massengill, K. Rolla, R. Cambria, C. Houston, A. Rodavitch Memorial Sloan Kettering Cancer Center
- 40.* Standardization and Unification of Deficiency Language in Auditing and Monitoring
 M. McGinn, K. Yataghene Memorial Sloan Kettering Cancer Center
- 41.**Using Centralized Review of Queries to Improve Data Integrity, a Canadian Clinical Trials Perspective

 A. Goyal, E. Strom, S. Duric, S. Pardhan, S. Mulumba, J.M. Veigas, D. Gutierrez,
 R. Yogananthan, T. Jayasinghe, K. Sabate, M. Kirchmeyer, M. Artemakis,
 A. Topalovich, L. Baumann
 Princess Margaret Cancer Centre, University Health Network
- 42.* Deciding How to Decide: Let Your Values Be Your Guide J. Edwards, C. Knoerle, D. Jenkins, N. Wallace Siteman Cancer Center
- 43.* Creating a Positive QA Team Image and Strengthening the Auditor/Research Team Relationship C. Knoerle, J. Edwards, D. Jenkins, N. Wallace Siteman Cancer Center
- 44.* Epic Transitions: How to Prepare Your Staff for Enterprise-Wide Change E. Menne, K. Williams, E. Hawkins Siteman Cancer Center
- 45.* The Critical Need for Consistent Training for Clinical Research Professionals
 K. Jelinek, R. Amoah The Ohio State University Comprehensive Cancer Center James Cancer Hospital & Solove Research Institute
- 46.* Help is on the Way: A CTMS Training Solution at an NCI-Designated Cancer Center M. Farris, J. de Jong The University of Kansas Cancer Center

2019 Abstracts

- 47.* Peer-to-Peer Quality Chart Review A. Skafel, P. Steiding, S. Barajas, A. Ferdinando UCSF Helen Diller Family Comprehensive Cancer Center
- 48.* Heat Mapping Noncompliance to Better Target the Extent of Corrective and Preventive Action Plans and Training J.K. Morrison, S. Scott UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

49.* Educating the Next Generation of Clinical Researchers A. Ivey, L. Pettiford, T. George University of Florida Health Cancer Center

- 50.**Evolving Recruitment Strategies Through the Development of a Research Nurse Residency Program for New Graduates J. Feliu, D. Cline, B. Showalter University of Texas MD Anderson Cancer Center
- 51.* Winship Clinical Trials Office CRC/CRN and Data Manager Orientation Program T. Kurilo Winship Cancer Institute of Emory University

Trial Recruitment and Disparities Research

- 52.* Trial Recruitment & Disparities Research: How Multicenter Institutional Studies Can Improve Enrollment A. Bauchle, L. Sego, S. Edwards Indiana University Melvin and Bren Simon Cancer Center
- 53.* MNCCTN: Challenges to Opening a State-Wide Network and the Pathway to Success - A 2-Year Perspective M.L. Rahne, R. Leed, C. Stibbe, J. Alkire Masonic Cancer Center, University of Minnesota
- 54.**Planting a Seed: How Bringing Research to the Community Can Blossom Into Patients Making Informed Health Care Decisions and Participating in Clinical Trials
 C. Moss, E. Meisler, K. Hunt, D. Allen, C. Hugney, S. Abraksia The Cleveland Clinic Cancer Center
- 55.* C3OD, An Abstraction and Recruitment Tool D.P. Mudaranthakam, J. Thompson, D. Streeter The University of Kansas Cancer Center
- 56.* The Impact of Modifying Eligibility Criteria on Accrual to Cancer Clinical Trials

D.P. Mudaranthakam¹, J. Thompson¹, D. Streeter¹, J. Unger², M. Fleury³ ¹The University of Kansas Cancer Center; ²Fred Hutchinson Cancer Research Center; ³American Cancer Society Cancer Action Network 57.•*Enhancing Accruals via Automated Performance Monitoring A. Ivey, T. George, A. Anderson, W.J. Stokes, H. Koranne University of Florida Health Cancer Center

Trial Start-up/Closure

- 58.* Clinical Trials Office New Study Committee: A Streamlined and Collaborative Approach for Clinical Trial Portfolio Management K. Krul, S. Bigelow, M. Kelley, L. Lange Barbara Ann Karmanos Cancer Institute, Wayne State University
- 59*The Need for Speed: Piloting a Study Activation Committee S. Flores, N. Sender, L. Blumberg, L. Segall, S. Mistretta, J. Wang, L. Butaud-Rebbaa, Q.-D. Quiles, T. Negri, M. Kelsen, F. Brogan, D. Otap, N. Rizzo Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center
- 60.* Improving Efficiency and Time Management During the Site Selection Process: A Collaborative Approach
 L. Lujan, S. Sharry, J. Moehle, T. Werner, E. Constantz, J. Espinosa, S. Fairbairn,
 B. Johnson
 Huntsman Cancer Institute, University of Utah
- 61.* Interdisciplinary Approach to Research Biopsy Acquisition in Oncology Clinical Trials
 K. Schroeder¹, J. Roessler², S. Zindars¹, M. Rau¹, E. Polak², J. Fleischman¹
 ¹Medical College of Wisconsin Cancer Center; ²Froedtert Hospital
- 62.* How Does a Master CDA Affect Timelines? C. Mackay¹, J. King² ¹The University of Kansas Cancer Center; ²Covance
- 63.* Value of Centralized Pre-Study Process A. Roberts, S. Davidson, N. Streeter, C. Mackay The University of Kansas Cancer Center
- 64.* Enhancing the Voice of Clinical Research Staff in the Trial Feasibility Process
 A. Daniels, A. Anderson, A. Ivey, T. George, L. Pettiford University of Florida Health Cancer Center
- 65.* Increasing Activation Transparency With Research Insights Dashboards E. Rocco, N. Licht, N. O'Dell, R. Arzoomanian, T. Johnson Yale Cancer Center, Yale School of Medicine
- 66.* Empowering Study Teams to Improve Clinical Trial Activation Timelines E. Rocco, N. Licht, N. O'Dell, T. Johnson, R. Arzoomanian Yale Cancer Center, Yale School of Medicine

AACI CRI Supporters

AACI gratefully acknowledges support from the following:

Platinum Level



Gold Level



Silver Level





Bronze Level



AACI Corporate Roundtable Members

AACI is grateful for the support of the 2019 Corporate Roundtable Members:

abbvie

















AACI CRI Exhibitors

AACI gratefully acknowledges support from the following:



AACI CRI Exhibitors

Advarra

Advarra is the premier provider of IRB, IBC, and global research compliance and administration consulting services in North America for clinical trial sponsors, CROs, hospital systems, academic medical centers, and investigators.

With the acquisition of Quorum and Kinetiq, Advarra provides the greatest institutional reach of any IRB, unmatched regulatory expertise, and One-Touch Collaboration™ to accelerate innovation, support faster study startup, and help make research altogether even better.

Offering profound expertise backed by proven central IRB infrastructure, Advarra's Central Oncology Review (COR) service provides specialized review by experts in oncology research and institutional human subject protection programs. Advarra is proud to have been selected as the central IRB for Academic and Community Cancer Research United (ACCRU) and as the single IRB (sIRB) for the NCI Cancer Moonshot Biobank.

Aerotek

Twenty-first century business demands agility, and you need the right people to succeed. As your staffing partner, Aerotek[®] assists your organization by providing the clinical research professionals needed to help you win in your unique industry.

Whether you need an experienced clinical research associate or a medical writer, we can help. As a Best of Staffing[®] leader, Aerotek gets to know every customer beyond the job description or resume, building quality relationships that allow us to place quality people in quality jobs.

As a leader in recruiting, staffing, and strategic outsourced solutions, we have over 250 non-franchised offices, serving 18,000 clients and employing more than 16,000 clinical and scientific employees every year — whatever the therapeutic area.

To learn how we can connect you with qualified clinical research talent, visit **Aerotek.com**.

ASCO Research Community Forum

The ASCO Research Community Forum (RCF) serves as a go-to resource for the oncology research community, including physician investigators, research staff, and community- and academic-based research programs.

The Forum's key objectives are to: 1) provide a forum for research teams to network and collaborate, discuss challenges and share best practices, and develop strategies and solutions to common challenges in conducting and managing clinical trials; and 2) develop solutions to address barriers to conducting clinical research and facilitate clinical trial participation and accrual.

The ASCO RCF is also holding an Annual Meeting on September 22-23, 2019, in the DC metro area, where physician investigators and research staff come together to network, collaborate, and develop solutions to common challenges.

Check out the ASCO RCF website, **asco.org/research-community-forum**, to learn more about the meeting and to access free resources and tools to support cancer research sites.

Cognizant

Cognizant is a leading global technology and services company. Its Life Sciences business unit partners with healthcare enterprises across the value chain to develop strategies and apply solutions to the challenges that matter.

Our services and products, including the Shared Investigator Platform (SIP), are digitizing interactions between sponsors, investigators, patients, and regulators across every phase, helping the industry subtract time from clinical development and add it to patient lives.

To learn more, visit **cognizant.com/life-sciences**.

Complion

Complion's mission is to reinvent site regulatory and document management by eliminating human error and redundant work to achieve maximum efficiency and compliance. We are the first and are the largest eRegulatory platform built for sites, health systems, academic medical centers, and cancer centers.

DEEP 6 AI®

Deep 6 Al[®] uses artificial intelligence and natural language processing on medical records so you can find and validate the patients you need to run a successful trial...in a matter of minutes.

Designed to put recruitment power into the hands of researchers, Deep 6 transforms trial criteria into an Al-powered search query. The tool then lets research staff search both structured and unstructured medical data—like physician's notes and pathology reports—so they can find and screen more, better-matching patients for their most complex trials more quickly.

The Deep 6 platform is EMR-agnostic and allows users to identify, screen and recruit patients in a HIPAA and IRB-compliant manner.

Deep 6 AI was founded in 2015 and is based in Pasadena, CA. Come visit our table or find out more at: **https://deep6.ai/**.

Florence

Florence advances clinical trials through software for managing document and data flow between research sites and sponsors.

Florence eBinders is trusted by 4,500+ investigators to manage eRegulatory/ eSource for over 1,000 studies and is the leading solution for cancer institutes.

Florence eTMF is the most flexible eTMF on the market with a wide range of innovative features, and Florence eHub is revolutionizing site-sponsor connectivity in a virtual site workspace for site oversight, monitoring, startup, and quality control.

Forte

Forte provides software and services in the critical areas of clinical trial management, clinical data management, and research administration for cancer centers, academic medical centers, and health systems.

With a strong belief in community, collaboration, and standards-based development, Forte also facilitates the Onsemble Community, a customerexclusive group for peer networking, best practices, and support. Twice a year at the Onsemble Conference, clinical research professionals meet in person and discuss the latest challenges and solutions in clinical research.

Forte provides all research professionals complimentary blog articles, eBooks, webinars, and more to support continuous learning on industry topics.

HealthMyne

HealthMyne is an integrated platform that extracts quantitative imaging metrics and combines that data with clinical information from the EMR, PACS, radiation therapy, and other systems to drive transformed clinical decision support workflow modules (Cancer Screening/Tumor Conference/Therapy Response/ Incidental Findings/Thoracic), actionable quantitative reports, and an integrated imaging and clinical patient-centric dashboard (PatientCare Timeline®) to optimize collaboration among the multidisciplinary care team.

Huron

Huron is a global professional services and software firm committed to achieving sustainable results in partnership with its clients.

The company brings depth of expertise in strategy, technology, operations, advisory services and analytics to drive lasting and measurable results in the healthcare, higher education, life sciences and commercial sectors.

Through focus, passion and collaboration, Huron provides guidance to support organizations as they contend with the change transforming their industries and businesses.

mint Lesion

An intelligent radiology assistant for structured reporting and standardized data mint Lesion is a software solution that combines diagnostic image viewing with a new, computer-assisted approach to standardize a radiologic read. It is an intelligent assistant which provides context-specific guidance for radiologists to increase read efficiency and reporting quality.

With an extensive array of standardized criteria and the continuous addition of new ones, mint Lesion can be successfully applied for clinical trials, routine radiology assessment, and imaging biomarker research such as radiomics. It ensures longitudinal transparency of disease, reproducibility of measurements, and criteria conformity.

The collected structured data can be easily linked with further information, like patient genomics, and analyzed through our real-time data analytics tool. Mint is an FDA-cleared medical device and provides a HIPAA-compliant audit trial.

PFS Clinical

PFS Clinical is dedicated to helping research institutions improve the management of their clinical trials from study start-up to final payment. Our service lines, which align with the various stages of a clinical trial, are Initiate: Study Start-Up, RevGuard: Financial Management, and Boost: Consulting & Training.

With Initiate, we provide on-demand study initiation services for contracts, budgets, coverage analyses, negotiations, and CTMS calendar builds.

With RevGuard, we manage your research billing processes, including financial tracking/reconciliation, financial reporting, and claims review, so you can focus on patient outcomes.

Our Boost consultants collaborate with your team to improve your research programs through workflow redesign, physician compensation plans, and flexible education and training.

If you're looking for a partner to be an extension of your research team, look to PFS Clinical. For more information, please visit **www.pfsclinical.com** or email questions@pfsclinical.com.

WCG

WCG is the world's leading provider of solutions that measurably improve the quality and efficiency of clinical research. The industry's first clinical services organization, WCG offers solutions that accelerate the delivery of new therapies to patients.

WCG Velos offers global, clinical research management software (CRMS) for cancer centers, academic medical centers, hospitals, health systems, clinical research sites, and sponsors. For more than two decades, Velos has facilitated efficiency, quality, and compliance in clinical research with a focus on cancer centers, supporting study and protocol management, electronic data capture, financial management, protocol review and IRBs, biospecimen management, and more.

WCG Velos users become part of the WCG Global Research Network[™] (GRN) which provides clinical researchers with access to sponsors and peer sites for collaboration and visibility. Through WCG's unique relationship with sponsors, CROs, research sites, and patient advocacy groups, GRN member sites have access to roundtables with sponsors and CROs, webinars, CenterWatch resources, and benchmarking data.

Work (and play) in one of the consistently-ranked best places to live in the Midwest: **MADISON, WISCONSIN**



The University of Wisconsin Carbone Cancer Center is hiring! Check out our open management and clinical research positions.

LEARN MORE Visit cancer.wisc.edu/jobs or e-mail cancercenter@mailplus.wisc.edu



Carbone Cancer Center UNIVERSITY OF WISCONSIN SCHOOL OF MEDICINE AND PUBLIC HEALTH



All the Advances that are Saving Lives Today are the **Result of Clinical Trials**

The Lurie Cancer Center would like to thank our CLINICAL TRIALS TEAM Your skill and dedication makes "exceptional" progress possible!



cancer.northwestern.edu/research

Trusted by More Cancer Centers than any other eRegulatory Solution

- Ensure comprehensive trial documentation, with fewer incomplete or missing documents
- Improve version control across teams to ensure all documents are up to date and in one location
- Standardize processes and automate workflows to ensure adherence to SOPs

Complion

- Identify quality metrics to inform operations and process improvements
- ♂ Achieve audit-readiness and 21 CFR 11 compliance



FORTE

Transforming clinical research with a site-centric approach

Gain comprehensive visibility into your research operations, enhance compliance across your enterprise and enable strategic decision-making with our integrated portfolio of standards-based solutions, including:



Manage finances, protocol lifecycle and patient lifecycle with the industry-leading enterprise research management system.



Enhance regulatory compliance, boost staff productivity and make your trials more efficient while decreasing time and cost.



Identify trends, spot problem areas and improve your research operations using comprehensive data visualization dashboards.

See what's new from Forte: Stop by our booth to learn more about the solutions above, and get a sneak peek at new multi-site regulatory management in Forte eReg!



2019 AACI/CCAF ANNUAL MEETING



NOTES