

P S OFFICES **DR 2021 AND**

13th Annual AACI CRI Meeting JULY 13-15, 2021

AACI CRI 2021 Steering Committee

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

Chair-Elect – Tara L. Lin, MD *The University of Kansas Cancer Center*

Tiffany Colvin, CCRC University of Colorado Cancer Center

Thomas J. George, Jr., MD, FACP University of Florida Health Cancer Center

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

Collette M. Houston Memorial Sloan Kettering Cancer Center Kimberly F. Kerstann, PhD Winship Cancer Institute of Emory University

Patricia M. LoRusso, DO, PhD Yale Cancer Center, Yale School of Medicine

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

Bhanu Pappu, PhD, MHA UPMC Hillman Cancer Center

Michael Sainz Dartmouth-Hitchcock Norris Cotton Cancer Center

Anne Schnatterly, MBA, BSN, RN, CCRP WVU Cancer Institute

Meeting Access and Social Media

Meeting sessions and presentations, exhibitor information, and a list of attendees are available on the Attendee Hub meeting website at https://cvent.me/avyL3v.

To access the Attendee Hub, log in with your name and email from registration. You will receive a 6-digit verification code at this email address or the mobile phone you provided at registration. Enter your 6-digit code and click "Log In."

Twitter: @AACI_Cancer Facebook: AACICancer Hashtag: #CRI2021

AACI CRI Welcome

he Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) program serves as a network for research leaders to develop and share best practices for the efficient operation of clinical trials offices at AACI cancer centers. The programming of the 13th Annual AACI CRI Meeting, Adapting Clinical Trials Offices for 2021 and Beyond, aligns with CRI's strategic goal of stimulating cancer center interactions to maximize resources by creating opportunities for peer-to-peer networking and collaboration.

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. Increase engagement with industry and other stakeholders to support CRI
- 7. Create a network for clinical trials office medical and administrative directors to foster communication and mentoring opportunities

AACI CRI Meeting Objectives

- Adapt to new policies to improve clinical trials office (CTO) operations that have come to the forefront as a result of COVID-19, including remote monitoring, eConsent, and staff training
- Recognize the impact of time gaps between trial approval and activation and learn steps to streamline the trial activation process
- Discern how knowledge of a center's catchment area can enhance community engagement opportunities with rural and/or underrepresented populations
- Understand updates to the National Cancer Institute's (NCI) Clinical Trials Reporting Program and revisions to the NCI funding opportunity announcement
- Learn how cancer centers have adapted to and prepared for virtual Cancer Center Support Grant reviews
- Identify the key differences between quality assurance and compliance and implement best practices for remote monitoring, risk-based monitoring, and sharing audit findings
- Apply new methods for recruiting and retaining qualified CTO staff, such as flexible work schedules and remote training options
- Optimize information already present in an institution's electronic medical records to save time and capture critical clinical research documentation
- Understand how cancer centers have integrated existing systems with the Shared Investigator Platform (SIP), and how interface enhancements to the SIP will impact future implementation

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
- Employees of 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
- Information technology companies that support cancer center clinical research management
- Like-minded organizations promoting patient access to clinical trials

MEETING PROGRAM

13th Annual AACI Clinical Research Innovation Meeting

Tuesday, July 13 – Thursday, July 15 | **Virtual Meeting** All session times are in Eastern Daylight Time.

Tuesday, July 13

10:00 AM Exhibits Open

11:00 AM Welcome

Theresa L. Werner, MD Huntsman Cancer Institute, University of Utah

A Message From Florence

11:20 AM All the Things We Never Want to Give Up Post-COVID Brought to you by Florence

While the coronavirus pandemic can't end too soon for clinical trials offices (CTOs), some operational responses have made life easier for CTO staff and may have staying power. Trial design adaptations and a broad embrace of digital modernization, including remote monitoring and management and eConsent, are among the beneficial "new normal" changes. Panelists will explore various COVID-19 measures in CTOs that may continue in a post-pandemic world, as well as unique challenges such as onboarding new staff during the pandemic, maintaining morale, and impacts on workflow and research operations.

Moderator: Thomas J. George, Jr., MD, FACP University of Florida Health Cancer Center

Andrea Kukla, MS Mayo Clinic Cancer Center

Vicki Sallée, PhD, MS, RD Abramson Cancer Center of the University of Pennsylvania

Susanna Sellmann, MRT, BSc, CCRP Princess Margaret Cancer Centre, University Health Network

12:25 PM Shared Investigator Platform Update

Panelists will share cancer centers' experiences with implementing Cognizant's Shared Investigator Platform (SIP). Other topics include the integration of other applications and research platforms to transfer information into the SIP, upcoming interface enhancements planned by Cognizant, and how the SIP is assisting sponsors with trial site selection.

Moderator: Tiffany Colvin, CCRC

University of Colorado Cancer Center

Lestter Cruz Serrano, MD, BCMAS

Cognizant Life Sciences

Lindsay Philip Princess Margaret Cancer Centre, University Health Network

Amber L. Voorhees Moffitt Cancer Center

Jeffrey Wagner

Eli Lilly and Company

1:25 PM Visit With Exhibitors

1:55 PM Break

2:10 PM Optimizing the Clinical Trials Office

Recruiting and retaining qualified clinical trials office staff requires creativity and flexibility, even more so during an infectious disease crisis that has altered many standard workplace practices. Topics include the rapid spread of work-from-home arrangements and the resulting pressure to keep staff connected. Panelists will also discuss succession planning, promoting staff to leadership positions, remote training, and the role of nurse coordinators.

Co-Moderator: Bhanu Pappu, PhD, MHA UPMC Hillman Cancer Center

Co-Moderator: Anne Schnatterly, MBA, BSN, RN, CCRP WVU Cancer Institute

Alison Ivey, RN, BSN, OCN, CCRP University of Florida Health Cancer Center

Brandi Showalter, PhD, RN, CCRP The University of Texas MD Anderson Cancer Center

3:15 PM Capturing Clinical Research Documentation in the EMR

Optimizing information already present in an institution's emergency medical record (EMR) can save time and decrease errors created by manual transcription of this information in electronic case report forms. Panelists will also discuss how institutions are creating fields to allow health care providers to better capture critical clinical research documentation.

Moderator: Theresa Cummings, RN, MS, CCRC

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

Chloe Fournier, MBA, CCRP Duke Cancer Institute, Duke University Medical Center

Mehek Mohan Genentech

Dinesh Pal Mudaranthakam, MBA

The University of Kansas Cancer Center

4:00 PM Exhibits Close

4:20 PM Extending Regulatory Workflow Efficiencies Post-Pandemic

Vendor Presentation: Complion

The University of Cincinnati (UC) Cancer Center leveraged an eRegulatory solution to achieve a 250 percent increase in clinical studies during COVID-19. UC Cancer Center will share some lessons learned in its pursuit of a paperless future, including building standard operating procedures and workflows around the electronic binder; using e-signatures on all documents; implementing electronic attestation of compliance training; and eliminating a physical trial master file.

Rick Arlow

Complion

Christine Vollmer

University of Cincinnati Cancer Center

4:50 PM Closing Remarks

Wednesday, July 14

9:30 AM How St. Jude Shifted From Reactive to Proactive to Enable Their Clinical Research Teams

Vendor Presentation: Veeva

For many years, people accepted the challenges of clinical research operations and management with a "This is how it is" attitude. They've been resilient and have plugged away for the sake of their patients and the mission of clinical research. But there are systems that can do a lot of the hard work and enable people to focus on the work that matters most – being with patients. Join us to hear how St. Jude Children's Research Hospital shifted from reactive clinical research management to proactive workflows with Veeva, enabling their site to embrace the future of clinical research.

Bree Burks, RN, MSN Veeva

Erin Kelly St. Jude Children's Research Hospital

10:00 AM Exhibits Open

10:00 AM Topic-Based Breakout Sessions View session descriptions

11:00 AM Welcome

A Message From Caris Life Sciences

11:10 AM Keynote Presentation

Brought to you by Caris Life Sciences

After being in various stages of treatment and advocating for patients for 24 years, Dicey Scroggins strives to help narrow the gaps between cancer centers and their communities. She will discuss her personal journey through clinical trials and their impact on patients and cover broader topics including diversity of clinical trial participants, personalized medicine, and global health equity.

Mary "Dicey" Scroggins, MA International Gynecologic Cancer Society

12:15 PM Defining and Improving Quality Assurance and Compliance

Identifying the difference between quality assurance and compliance can lead to major improvements in clinical trials office operations. What is the right volume of investigator-initiated trials that should be monitored? What information should be audited instead of monitored? Panelists will answer these questions and discuss best practices for remote monitoring, risk-based monitoring, and sharing audit findings with staff and physicians.

Moderator: Melissa Nashawati, MPA

Mays Cancer Center, UT Health San Antonio

Karla McNutt The University of Kansas Cancer Center

Monica A. Orians, BSMT, CCRC University of Michigan Rogel Cancer Center

Kelli Thorne, MPH, CCRP Huntsman Cancer Institute, University of Utah

1:15 pm Break

A Message From Caris Life Sciences

1:30 pm 2021 CRI Abstract Presentations Brought to you by Caris Life Sciences

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

FIRST PLACE: Electronic Source Documentation in Epic Reduces Key Audit Findings and Aids in Remote Coordinating and Auditing N. Kurtzweil, M. Marcum, T. Wise-Draper University of Cincinnati Cancer Center

SECOND PLACE: A Catalyst for Success: How the I2T3 is Transforming IIT Development at UFHCC E. Monari, A. Ivey, T. George, A. Anderson University of Florida Health Cancer Center

THIRD PLACE: Doing More With Less: The Adoption of Slot Management Practices to Drive Resource Allocation in the Clinical Trials Office C. Gregor

Vanderbilt-Ingram Cancer Center

Moderator: Theresa L. Werner, MD Huntsman Cancer Institute, University of Utah

Catherine Gregor, MBA, CCRP, CCRC Vanderbilt-Ingram Cancer Center

Nicky Kurtzweil, JD, CCRP University of Cincinnati Cancer Center

Erin Monari, PhD, CCRP University of Florida Health Cancer Center

2:35 PM Poster Session

Brought to you by Veeva

Abstract authors will share challenges they experienced within their clinical trials office and the innovative solutions implemented to improve cancer center operations.

Moderator: Theresa L. Werner, MD

Huntsman Cancer Institute, University of Utah

Mason Dworak

Masonic Cancer Center, University of Minnesota

M. Alison Kannon

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

Jacquelin Mohr, MS Memorial Sloan Kettering Cancer Center

Brett Palmer, MS, CCRC

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

Josh Plassmeyer, MS, CCRP

UPMC Hillman Cancer Center

Kaitlin Stephens, MBA, CCRC

Huntsman Cancer Institute, University of Utah

Katherine Zeman

Princess Margaret Cancer Centre, University Health Network

3:40 PM Advancing Oncology Research: Safer, Smarter, and Faster

Vendor Presentation: Advarra

NCI-Designated Cancer Centers rely on a wide range of complex processes, enterprise technology, specialized staff, and sophisticated programmatic structures to improve study start-up timelines and ensure trials run smoothly. While centers have made significant progress in understanding their programs and increasing efficiency, there's still work to be done. In this session, Dr. Wendy Tate of Advarra will outline the people, process, technology, and integrated workflows needed to accelerate research.

Wendy Tate, PhD, MS, GStat Advarra

4:00 PM Exhibits Close

4:10 PM Closing Remarks

Thursday, July 15

10:00 AM Exhibits Open

10:00 AM Role-Based Breakout Sessions View session descriptions

11:00 AM Welcome

11:10 AM Community Outreach and Engagement: Knowing Your Catchment Area

Successful community outreach requires more than connecting with your organization's Community Outreach and Engagement office. An intimate understanding of the catchment area is key for a range of interactions and can help identify engagement opportunities and extend clinical trial access to the community. Panelists will discuss methods for working with satellite sites, bridging the gap between rural communities and cancer centers, and eliminating barriers for patients visiting the main cancer center.

Moderator: Collette M. Houston

Memorial Sloan Kettering Cancer Center

Mark Doescher, MD, MSPH Stephenson Cancer Center, University of Oklahoma

Timothy R. Rebbeck, PhD Dana-Farber Cancer Institute, Harvard Medical School

Linda Robertson, DPH, MSN, BSN UPMC Hillman Cancer Center

12:10 PM Visit With Exhibitors

12:40 PM Break

12:55 PM Breaking Down Trial Activation and Timelines

Multiple factors can determine when a clinical trial begins and time for completion. Identifying and controlling these variables can improve the activation process and shorten trial timelines. Panelists will examine the impact of time gaps between trial approval to trial activation; working with sponsors; and which aspects of the activation process are controlled by the clinical trials office, health system, or university and ancillary committees. Timeline definitions and benchmarking data from a recently completed AACI CRI survey will be included in the discussion.

Moderator: Patricia M. LoRusso, DO, PhD

Yale Cancer Center, Yale School of Medicine

Sean Jensen Merck

Katherine Rolla Simpson Memorial Sloan Kettering Cancer Center

Jered Sieren, MHA Holden Comprehensive Cancer Center, University of Iowa

2:00 pm NCI Cancer Center Support Grant: New Approaches to Addressing a Dynamic Environment

Panelists will discuss the experiences of cancer centers that have received Cancer Center Support Grant reviews, both in-person and virtually, during the coronavirus pandemic. In addition, National Cancer Institute (NCI) officials will provide updates on the clinical trials reporting program and revisions to the funding opportunity announcement (FOA), including the functions and impact of disease working groups, that took effect in 2020. Other FOA topics will include expectations for funding investigator-initiated trials, new catchment area definitions and adjustments to how community outreach and engagement is defined, and the role of the protocol review and monitoring committee.

Part 1

Moderator: Michael Sainz Dartmouth-Hitchcock Norris Cotton Cancer Center

Henry P. Ciolino, PhD National Cancer Institute

Gisele A. Sarosy, MD National Cancer Institute

Part 2

Moderator: Kimberly F. Kerstann, PhD Winship Cancer Institute of Emory University

Parchayi Dalal, MPH, CCRC University of Virginia Cancer Center

David Gosky, MA, MBA

The Ohio State University Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute

Erin Williams, MBA

Simmons Comprehensive Cancer Center, UT Southwestern Medical Center

3:35 pm Accelerating Study Activation and Finding the Right Trials for Patients

Vendor Presentation: Essex Management

Cancer centers face challenges opening clinical trials to enrollment as fast as possible and helping treating clinicians find appropriate trials for patients. Study activation workflows are often done manually and are consequently inefficient, causing delays due to lack of visibility and unnecessary obstacles. Finding trials that match a patient's disease, molecular mutations, demographics, and past treatment can be difficult at best, even within an institution, since there is no centralized source of information or way to search available data. In this talk, Essex will describe methods and tools that have successfully streamlined study activation, as well as approaches under development, to find the right clinical trial for each patient.

David Loose

Essex Management

Eve Shalley

Essex Management

4:05 PM Closing Remarks

5:00 PM Exhibits Close

AACI CRI Meeting 2021 Abstracts

FIRST PLACE: Electronic Source Documentation in Epic Reduces Key Audit Findings and Aids in Remote Coordinating and Auditing N. Kurtzweil, M. Marcum, T. Wise-Draper

University of Cincinnati Cancer Center

SECOND PLACE: A Catalyst for Success: How the I2T3 is Transforming IIT Development at UFHCC E. Monari, A. Ivey, T. George, A. Anderson

University of Florida Health Cancer Center

THIRD PLACE: Doing More With Less: The Adoption of Slot Management Practices to Drive Resource Allocation in the Clinical Trials Office

C. Gregor

Vanderbilt-Ingram Cancer Center

Additional abstracts are organized by category.

Clinical Trial Operations

1. Operationalizing a New Therapy Across Research Groups: A Team-Based Approach to Managing CAR T Clinical Trials L. Waitkus

Cleveland Clinic Cancer Center

- 2. COVID Response: Providing Ongoing Oncology Clinical Research Support During a Pandemic B. Oleson, J. Thomas, J. Bollmer, K. Schroeder, D. Pastorek, P. Jacobs, M. Pigsley, S. Zindars, G. Coly Medical College of Wisconsin Cancer Center
- 3. Automating Protocol Training Documentation: Regulatory Compliance in a Click R. Lehrman, P. Lim, C. Abate, J. Buthorn, A. Foster, E. Hamilton, H. Kiesler, K. Yataghene Memorial Sloan Kettering Cancer Center
- 4. Clinical Trial Finder A Comprehensive Mobile Application D. Mudaranthakam, V. Murakonda, A. Tribitt, J. Scott, B. Broome, J. Thompson, M. Mayo, B. Gajewski, T. Lin The University of Kansas Cancer Center

- 5. OPTIK Organize Prioritize Trends to Inform KU Cancer Center Members D. Mudaranthakam, L.M. Harlan-Williams, H. Krebill, H. Kuo, D. Koestler, Q. Xia, R. Chen, L. Chollet-Hinton, M. Mayo, R. Jensen The University of Kansas Cancer Center
- 6. Cross-Modality Reconciliation for Management and Reporting of All **Cancer-Related Clinical Research Data** C. Serway, E.D. Merchasin, R.C. Compton, U. Brown-Glaberman, C.Y. Muller University of New Mexico Comprehensive Cancer Center
- 7. We Have 99 Problems But a Participant Withdraw is No Longer One S. Bigelow, C. Galasso, J. Ventimiglia, L. Casetta, C. Zuccaro, J. Mancini Barbara Ann Karmanos Cancer Institute, Wavne State University

- 8. Executing a Healthy Volunteer Study During COVID-19 Pandemic P. Herena, M. Licata, R. Stan, C. Wood, A. Yi, M. Shields City of Hope Comprehensive Cancer Center
- 9. Increasing the Utilization and Efficiency of a Phase 1 Program to Support Pan-Tumor Clinical Trials J. Tomer, K. Gardner, J. Southard

Cleveland Clinic Cancer Center

- Harness the Power of Automation for Clinical Research Management
 D. Wilson, R. Kingsford, L. Hayes, J. Moehle, T. Werner
 Huntsman Cancer Institute, University of Utah
- A Quality Connection... An Enhanced Leadership Structure Through the Implementation of a Project Administrator
 L. Lujan, S. Sharry, R. Kingsford, J. Moehle Huntsman Cancer Institute, University of Utah
- Smooth Sailing... Cellular Immunotherapy Trials Collaboration and Integration Process
 S. Sharry, C. Cromar, K. Hicks, L. Lujan, J. Moehle, K. Pena Huntsman Cancer Institute, University of Utah
- 13. Team Connection During COVID J. Espinosa, C. Marshall, A. Horstmeier, J. Moehle, L. Lujan Huntsman Cancer Institute, University of Utah
- *There and Back Again: A Satellite Site Operations Tale
 B. Glenn, K. Stephens, A. Horstmeier, E. D'Astous, J. Moehle, T. Werner
 Huntsman Cancer Institute, University of Utah
- Establishing an Employee Engagement, Equity, and Education Committee During Remote Operations

 Feola, M. Kimber, A. Hoeschen, M. Dworak, M. Loza

 Masonic Cancer Center, University of Minnesota
- Transformative Lessons for Clinical Trials From the COVID-19 Pandemic: Remote Monitoring, Virtual Research Visits, and Added Flexibility for Patients

 G. Malave, A. Fritsche, K. Croghan, J. Jensen, J. Burton, J. Pickett, H. Finnes, J. Judge, J. Bruggeman, J. Welter, S. Alberts, S. Kumar

Mayo Clinic Cancer Center

 Structured Collaboration With Clinical Partners to Enhance Research Participant Safety and Experience Along With Protocol Compliance and Expeditious Trial Activation
 Willoughby, C. Davis

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

 Incorporating the Complexity of Screening Into Protocol Acuity: Updates to the SCCC Staff Scoring Model
 E. Siglinsky, K. Crane, S. Grant, S. Meletath, A. Neal, H. Phan, S. Goksu, M.S. Beg, E. Williams

Simmons Comprehensive Cancer Center, UT Southwestern Medical Center

2021 Abstracts

19. Does Mentorship Improve CRC Retention Rates and Employee Satisfaction? E. Pon, E. Nurminen, M. Welsh, M. Narwal UCSF Helen Diller Family Comprehensive Cancer Center 20. Transitioning to Remote Monitoring Visits at the Helen Diller Family **Comprehensive Cancer Center** M. Kock UCSF Helen Diller Family Comprehensive Cancer Center 21. From Take-Off to Landing: The Creation and Implementation of a CCPS **Navigator Resource** A. Trainor, A. Ivey, T. George, L. Pettiford, A. Anderson University of Florida Health Cancer Center 22. Implementation of Electronic Informed Consent for Cancer-Relevant **Clinical Trials at the UFHCC** A. Riggs, T. Toon, A. Anderson, A. Ivey, T. George University of Florida Health Cancer Center 23. Doing More With Less: The Adoption of Slot Management Practices to Drive Resource Allocation in the Clinical Trials Office C. Gregor Vanderbilt-Ingram Cancer Center 24. Adapting Adverse Event Log Creation During COVID-19: Development of the Winship eAE Log Application D. Smith, M. Ellingson, V. Parker, M. Martin, T. Adewuya, P. Bourbo, S. Brown, L. Cox, M. Williams, L. Floyd, B. Gamble, M. Hananel, T. Kurilo, A. Lesinski, K. Nguyen, C. Shah, C. Sharp, A. Trumbull, A. Overby, M. Behera

Winship Cancer Institute of Emory University

Finance/CCSG/PRMS

- 25. Staff Effort Estimate Calculator: A Successful Multisite Program Budget and Staffing Tool A. Hinman, A. Baim, A. Carabajal, R. Selle, B. Oleson, J. Thomas Medical College of Wisconsin Cancer Center
- 26. Statistically Significant Impacts of a PRMC Charter Alignment With NCI Practices
 C. Vollmer, T. Herzog, C. Allen, N. Kurtzweil, E. Chandra, B. Hughes
 University of Cincinnati Cancer Center
- *MSK's NCI Network Program

 Mohr, L. Gaffney, C. Houston, M. Warren, C. Aghajanian, P. Sabbatini, E. Cottington, S. Ramaswami, B. Zakrzewski, J. Klinger, S. Dominguez, S. Terzulli, J. Nunner, A. Rodavitch, K.R. Simpson, S. Hanley Memorial Sloan Kettering Cancer Center
- 28. Enhancing the DSG Review at the UFHCC J. Walsh, T. Guinn, A. Anderson, A. Ivey, T. George University of Florida Health Cancer Center

Investigator-Initiated Trials

29.	*Use of R-Scripts Can Help to Decrease Time and Improve Accuracy on
	Summary Tables for IND and Semi-Annual Reports
	B. Palmer, A. Brikha, F. Lin, J. Woodman
	Robert H. Lurie Comprehensive Cancer Center of Northwestern University

- 30. Managing Investigator-Initiated Clinical Trials Registration to Reduce Overall Reporting Errors at a Consortium Cancer Center K. Hoy, A. Savadelis, A. Firstencel, H.J. Pounardjian Case Comprehensive Cancer Center
- 31. Development, Management, and Oversight of Investigator-Initiated Multicenter Trials

J. Walkley, M. Warren, K. Muenkel, S. Hughes, C. Friedman, C. Houston Memorial Sloan Kettering Cancer Center

32. A Catalyst for Success: How the I2T3 is Transforming IIT Development at UFHCC

E. Monari, A. Ivey, T. George, A. Anderson University of Florida Health Cancer Center

Regulatory

- 33. Implementation of a Fully Electronic Regulatory Binder for Clinical Trials During COVID Pandemic C. Kennedy, B. Sharp, K. Penas Fred and Pamela Buffett Cancer Center
- 34. Fast Financials: An Automated Approach to Financial Disclosures A. Foster, J. Buthorn, A.M. Gonzalez-Dadiz, K. Yataghene Memorial Sloan Kettering Cancer Center
- 35. Regulatory Team Increasing Efficiency and Reducing Footprint in the Office C. Vollmer

University of Cincinnati Cancer Center

- 36. Partnering With Foreign Collaborators and the Institutional Review Board to Document Human Subjects Protection Requirements for Sites Outside of the United States V. Santana, L. Faughnan, E. Fernandes, K. Prive, P. Naidu Comprehensive Cancer Center, St. Jude Children's Research Hospital
- 37. *Developing a Tool to Assess Regulatory Acuity and Workload M. Kannon, S. Scott

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

38. Regulatory Completion Timelines: A Prospective and Retrospective Analysis of the Effect of an eRegulatory System M. Kannon, S. Scott, J. Sweitzer, K.M.C. Blalock, P. Brock, A. Ciccotti, S. Williams, C. Worth

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

39. Implementing the Shared Investigator Platform at the UFHCC A. Anderson, T. Toon, A. Ivey, T. George University of Florida Health Cancer Center

Training, Quality Assurance, Remote Monitoring, and Auditing

40. Maintaining Specimen Compliance for a High Volume of Complex Clinical Trials

C. Johnston, A. Larsen, J. Cummings, J. Moehle Huntsman Cancer Institute, University of Utah

- Risk-Based Monitoring (RBM) Model: Safeguarding Single-Center, Investigational New Drug (IND), Investigator-Initiated Trials (IIT) at Memorial Sloan Kettering Cancer Center
 F. Puma, A. Granobles, K. Mantha-Thaler, K. Yataghene Memorial Sloan Kettering Cancer Center
- 42. Saved by Automation! How Technology and Innovative Thinking Significantly Increased Productivity of the MSK CR Audit Program S. Puleio, J. Simpronio

Memorial Sloan Kettering Cancer Center

- 43. Strengthening Monitoring/Auditing Collaboration With Sponsors A. Granobles, F. Puma, K. Yataghene, K. Mantha-Thaler, N. Cimaglia Memorial Sloan Kettering Cancer Center
- Demonstrating Safety and Necessity of Clinical Trials Deviations for Improving Flexibility and Inclusivity of Clinical Trials Enrollment Utilizing a Centralized Deviation Database
 M. Hullings, E. Williams, P. Dixit, C. Wynne-Jones, A. Gonzalez, M.S. Beg, D. Gerber Simmons Comprehensive Cancer Center, UT Southwestern Medical Center

 45. Creation of a Sponsor Quality Management Plan Under GCP Revision 2: Checks-and-Balances, Quality Systems, and Cross-Functional Communication

 J. Morrison, M. O'Dwyer, C. Conde, S. Maxwell, N. Babadi, R. Johnson, M.A. Kannon, S. Scott, J. Huamani-Bundy, C. Lee
 UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

- 46. Electronic Source Documentation in Epic Reduces Key Audit Findings and Aids in Remote Coordinating and Auditing N. Kurtzweil, M. Marcum, T. Wise-Draper University of Cincinnati Cancer Center
- 47. Remote Onboarding and Training in the Clinical Trials Office K. Rygalski, M. Russell, D. Kitterman

University of Illinois Cancer Center

 48. Reducing Turnover During a Pandemic: Growing Leaders at an NCI-Designated Cancer Center A. Rice-Warren, C. Fournier Duke Cancer Institute, Duke University Medical Center
49. Transitioning to Remote Monitoring: Challenges and Successes H. Finch, S. Matkin, K. Thorne <i>Huntsman Cancer Institute, University of Utah</i>
 50. *Equity and Diversity Initiatives Within a Cancer Center's Clinical Trials Office M. Dworak, M. Loza, D. Berkow-Schwartz Masonic Cancer Center, University of Minnesota
 51. Rolling With the Changes: Onboarding Staff Remotely During the COVID-19 Pandemic R. Selle, M. Gray, B. Oleson, J.P. Thomas Medical College of Wisconsin Cancer Center
52. Onboarding and Training New Staff While Working Remote During a Global Pandemic E. Laskowski, J. DeJong, H. Apell The University of Kansas Cancer Center

- 53. Ensuring the Next Generation of Clinical Researchers A. Anderson, L. Pettiford, A. Ivey, T. George University of Florida Health Cancer Center
- 54. Implementation of a Research-Specific, Electronic Orientation for Clinical Research Professionals

 A. Kukulka, A. Ivey, A. Anderson, T. George University of Florida Health Cancer Center
- 55. Implementation of Professional Competency Development Program for Clinical Research Professionals

 A. Kukulka, A. Ivey, A. Anderson, T. George
 University of Florida Health Cancer Center

Trial Recruitment & Community Outreach and Engagement

- 56. *Exploring the Perceptions and Satisfaction of Princess Margaret Clinical Trial Participants
 K. Zeman, S. Sellmann, H. Cole
 Princess Margaret Cancer Centre, University Health Network
- 57. Strengthening Connections: Integrating Clinical Trials Into Patient and Public Education
 G. Nachaegari, S. Fraser, D. Branson, J. Moehle, T. Werner
 Huntsman Cancer Institute, University of Utah

2021 Abstracts

Trial Start-up and Activation

- 58. Use of a Site Profile to Streamline Site Selection and Feasibility S. Zindars, J. Bollmer, B. Oleson, K. Schroeder, D. Pastorek, M. Pigsley, P. Jacobs, G. Coly, R. Selle, B. Steinert, A. Carabajal Medical College of Wisconsin Cancer Center
- 59. One Committee to Review Them All: A Single, Multidisciplinary COVID-19 Research Committee J. Migliacci, S. Hanley, A. Rodavitch Memorial Sloan Kettering Cancer Center
- 60. Study Start-up Activation Dashboard Improving Transparency L. Wall, A. Spratt, N. Connellan The University of Chicago Medicine Comprehensive Cancer Center
- *Strategies for Improving Time-to-Activation of Clinical Trials
 J. Plassmeyer, B. Marino, M. Yarkowski, M. Horak, H. Usman, D. Cleary,
 A. Wozniak, B. Pappu
 UPMC Hillman Cancer Center

OFfice Thinnan Cancer Center

62. Process Improvements to Shorten Clinical Trial Activation Times Within a National Cancer Institute-Designated Comprehensive Cancer Center S. Grant, M. Farmer Wake Forest Baptist Comprehensive Cancer Center

AACI CRI Supporters

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AACI CRI Exhibitors

Advarra

Advarra advances the way clinical research is conducted: bringing life sciences companies, CROs, research sites, investigators, and academia together at the intersection of safety, technology, and collaboration. With trusted IRB and IBC review solutions, innovative technologies, experienced consultants, and deep-seated connections across the industry, Advarra provides integrated solutions that safeguard trial participants, empower clinical sites, ensure compliance, and optimize research performance. Advarra is advancing clinical trials to make them safer, smarter, and faster. For more information, visit **advarra.com**.

Caris Life Sciences®

Caris Life Sciences is a leading innovator in molecular science focused on fulfilling the promise of precision medicine through quality and innovation. The company's suite of market-leading molecular profiling offerings assess DNA, RNA, and proteins to reveal a molecular blueprint that helps physicians and cancer patients make more precise and personalized treatment decisions. Headquartered in Irving, Texas, Caris Life Sciences offers services throughout the U.S., Europe, Asia, and other international markets. To learn more, please visit **CarisLifeSciences.com** or follow us on Twitter (**@CarisLS**).

Essex Management

Essex Management is a biomedical informatics and health information technology-focused consultancy founded in 2009, and headquartered in Rockville, Maryland. Our staff comprises experts with extensive experience in strategically managing and developing complex health and biomedical information programs for clients in the federal government, research academia, and private sectors.

Florence

Florence is the leading platform for remote connectivity and electronic document workflow management in clinical research. It is considered the industry standard, with more than 8,500 research sites, sponsors, and CROs in 34 countries collaborating on its network. Florence advances clinical trials through software for managing document and data flow between research sites and sponsors. Florence solutions foster 25 percent faster start-up time and 40 percent reduced document cycle time, among other benefits. To learn about advancing research through collaboration, visit **florencehc.com**.

AACI CRI Exhibitors

Huron

Huron's cancer center team is composed of leaders with 20-plus years of frontline experience in academic-based cancer centers. We rely on our firsthand 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. Our team has worked with over 75 aspiring and established cancer centers, notably assisting institutions in renewing or obtaining their first National Cancer Institute (NCI) designation award and designing a statewide, multi-institutional organizational structure for conducting clinical trials. We have extensive experience in the clinical research, clinical trials, and biotechnology spaces, spurring innovation and advancing knowledge.

nCoup

nCoup provides innovative cloud solutions that address operational needs of organizations conducting clinical research. nCoup recently launched nCartes, the next generation EHR to EDC clinical data transport platform that enables sites and sponsors to harness electronic medical records to populate EDC systems and fulfill clinical trials. nCartes has been proven to reduce the time and cost of data entry on some cancer clinical trials by 50 percent. nCoup leverages its extensive and deep EHR integration and clinical trials software expertise to deliver nCartes. nCoup, Inc. is privately held with headquarters in Fremont, California. For more information on nCoup, please visit **ncoup.com**.

Veeva

Veeva offers a suite of applications built specifically for research sites and institutions with connectivity to sponsors and patients to reduce complexity and advance research. With Veeva, you can focus less on technology and more on your research. Veeva Systems Inc. is the leader in cloud-based software for the global clinical research industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 875 customers, ranging from the world's largest pharmaceutical companies to emerging investigative sites.

WCG

WCG's Managed Research Solutions empower high-performing, competitive research programs by transforming clinical research – supporting more trials, more patients, and more time for a patient-centric approach. WCG offers a suite of purpose-built services and robust technology designed to optimize your research program. Decrease study start-up timelines by 37 percent, increase enrollment by 39 percent, and boost financial results by 21 percent. Our flexible, tailored approach enhances efficiency while ensuring quality and compliance. It's your research program, with our expert support.

WellSky®

WellSky is a technology company leading the movement for intelligent, coordinated care worldwide. Next-level software, analytics, and services power better outcomes and lower costs for stakeholders across the health and community care continuum. In today's value-based care environment, WellSky helps providers, payers, health systems, and community organizations solve tough challenges, improve collaboration for growth, harness the power of data analytics, and achieve better outcomes by further connecting clinical and social care.

Advarra's integrated solutions are designed to safeguard patients, empower clinical sites, ensure compliance, and optimize research performance. Together, we are working to make clinical research safer, smarter, and faster.

OnCore.

Streamline research operations with a comprehensive, proven, and standardized system built through collaboration with leading research organizations and used by more than 70% of NCI-designated cancer centers.

🔶 eREG.

Save time, improve workflows, and enhance regulatory compliance with the most comprehensive, integrated eRegulatory system available.

🔶 eConsent.

Keep patients engaged, ensure understanding, simplify oversight, and improve the overall consenting process at your center with Advarra eConsent.

🚺 IRB | IBC.

Accelerate the review process and ensure appropriate participant and community protections with the specialized oncology expertise of Advarra's IRB and IBC review services.

Join us:

Advancing Oncology Research: Safer, Smarter, and Faster Wednesday, July 14th | 3:40 pm ET



Predictor for mCRC

Molecular AI to Navigate mCRC Standard of Care Chemo Selection

Molecular AI is changing how we see cancer – and how we fight it.

Caris FOLFOXai[™], from Caris Life Sciences[®], is the first clinically validated, Al-powered molecular predictor of chemotherapy efficacy for mCRC patients. MI FOLFOXai[™] is intended to gauge a mCRC patient's likelihood of benefit from first-line treatment FOLFOX (plus bevacizumab) followed by FOLFIRI+BV, versus FOLFIRI+BV followed by FOLFOX+BV.

FOLFOXai[™] demonstrated that the overall survival (OS) of patients treated in a manner consistent with the FOLFOXai prediction was 17.5 months longer (71%) than the OS of patients treated counter to the prediction.¹

	FOLFOXai™ Indicates:		
Median Overall Survival	FOLFOX+BV 1 st ↓ FOLFIRI+BV 2 nd (FOLFOX+BV RWE cohort)	FOLFIRI+BV 1 ^s ↓ FOLFOX+BV 2 nd (FOLFIRI+BV RWE cohort)	
OS When Patient Received: FOLFOX+BV 1 st ↓ FOLFIRI+BV 2 nd	42.0 months	18.7 months	
OS When Patient Received: FOLFIRI+BV 1 st ↓ FOLFOX+BV 2 nd	24.5 months	34.4 months	

FOLFOXai[™] comes standard with every Caris Molecular Intelligence[™] colon cancer tumor profile at no additional cost, increased turnaround time or added specimen requirements. **Where Molecular Science Meets Artificial Intelligence.**

To order or learn more, please visit www.CarisLifeSciences.com/mi-folfoxai/ or contact your local Caris Representative.

Decisions on patient care and treatment must be based on the independent medical judgment of the treating physician, taking into consideration all available information concerning the patient's condition.

 Abraham JP, Korn WM, Spetzler DB, et al. Clinical validation of a machine-learning derived signature predictive of outcomes from first-line oxaliplatin-based chemotherapy in advanced colorectal cancer. Clin Cancer Res. 2020 Dec 8:clincanres.3286.2020. doi: 10.1158/1078-0432.CCR-20-3286. Epub ahead of print. PMID: 33293373.





Named one of the 10 best hospitals for Cancer care in the U.S.

At Cedars-Sinai, the dedication of our doctors and staff has made us one of the most recognized hospitals in the nation. We're proud to have earned a place on U.S. News & World Report's Best Hospitals Honor Roll and to be #1 in California for cancer care. This recognition belongs to our entire team, who shows up day after day, night after night, for all of Southern California.

We have exceptional opportunities for physician-scientists, clinical scholars, research scientists and clinical research staff to join our fast-growing academic cancer enterprise.

To learn more about these open positions and our Cancer Clinical Trials Office Medical Directorship opportunity, CLICK HERE.







Are you tired of fighting with messy binders, cluttered inboxes or misplaced documents?

Is the already heavy workload of tasks associated with the administration and management of regulatory and trial paperwork become even more compounded by COVID-19?

Do you want to reduce those tasks while improving your efficiency, compliance and transparency?

It's time to partner with Complion. Our cloud-based eReg solution enables you to:

- ✓ Quickly find the right document with better organized files, standard templates, and powerful keyword search.
- ✓ Reduce time managing PI delegation records, Safety Reports, CVs, Licenses and training with Part 11 compliant signatures and site-centric workflows.
- ✓ Eliminate printing and redundancy by connecting to existing email, CTMS, IRB or EMR systems without costly development or custom coding.
- ✓ Instantly collaborate across multiple sites and institutions.

Ready to learn more? Let's schedule a demo. Contact us at 800-615-9077 or info@complion.com.



essex

The technology catalyst for innovation in life sciences

ABOUT US

TEAM	Biomedical Research Informatics experts delivering solutions that advance science, on time and on budget
APPROACH	Committed to best practices in Program Management, Software Engineering, DevSecOps, Data Science, & Data Standards
ERFORMANCE	Leverage metrics to learn, adapt, and change continually improving performance & customer ROI
PROMISE	Mature administrative processes and a transparent customer-

PROMISE Mature administrative processes and a transparent, customerfocused attitude

PROGRAM & PROJECT MANAGEMENT

- Program Planning & Management
- Business Analysis & Design
- Stakeholder Management & Communications
- Subject Matter Experts
- Clinical Data Standards

CAPABILITIES

SYSTEM DESIGN & ENGINEERING

- Cloud Engineering
- Digital Transformation
- IT Systems Consolidation
- Application Engineering
- Machine Learning/AI/NLP
- Integrated Process Automation

COMPUTATIONAL BIOLOGY & BIOINFORMATICS

- Development of Genetics & Phenotypic Databases
- Development of Analytics / Algorithms
- Data Management
- Omics Analysis
- Design of Query Interfaces

SOLUTIONS





You have patient safety, drug accountability, protocols, investigator satisfaction, team management, grants, NCI designations, training, and a million things to think about when managing research operations and accelerating cures. Your regulatory and source documentation shouldn't be one of them.

Florence helps you, numerous AACI member institutes, and more than 8,500 study sites in 34 countries, optimize electronic document work lows and enable remote site access.

Learn more and see stories of other institutes using Florence to accelerate research.

FlorenceStories.com

Huron understands cancer centers.

Addressing the unique needs of the world's leading cancer centers:



Enhance clinical research operations.

Streamline research administration.

Provide strategic advice.

Prepare for National Cancer Institute designation.

huronconsultinggroup.com/insights/ strategic-solutions-cancer-centers

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Prepare Your Center for the Future of Clinical Research

Power your clinical research end-to-end with Veeva, a global leader in clinical research technology

Partner with Veeva for all your clinical trial technology needs from FDA submissions to electronic trial master files, EDC, eRegulatory, and source document management.

The difference? Veeva built the Clinical Network providing a direct, secure connection to exchange documents with sponsors and patients for faster and safer research operations.

We make it easy to switch to our modern, connected research technology. Join over 2,500 sites in 60+ countries that are using SiteVault to go paperless and run patient-centric trials.

Flexible partnership: we meet you where you're at with your needs. Join our AACI-CRI session on Wednesday, July 14th at 9:30am eastern to hear from a cancer center customer about their Veeva experience.

Contact us at go.veeva.com/aaci-cri to learn if SiteVault is a good fit for you.

ASCO[®] Clinical Cancer Advances



This Report Features:

- The Advance of the Year
- Ways to Achieve Health Equity in Cancer Research
- Research Priorities That Will Accelerate Progress



Read <u>Clinical Cancer Advances</u>, or learn more about <u>ASCO's research activities</u> and <u>evidence-based policy and advocacy activities</u>.



nCoup proudly introduces the nCartes EHR to EDC platform to the AACI Community



For more information, please visit nCoup in the virtual exhibit hall or at ncartes.ncoup.com

nCoup

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