ADAPTING CLINICAL TRIALS OFFICES FOR 2021 AND BEYOND

13th Annual AACI CRI Meeting

JULY 13-15, 2021

Medical Arts Building
3708 Fifth Avenue, Suite 503
Pittsburgh, PA 15213
Phone: 412-647-6111
www.aaci-cancer.org
The 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

**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

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Looking for presentations, exhibitors, or other attendees?  
Visit Attendee Hub
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
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

1:30 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
**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

**Mason Dworak, 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

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**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

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**Exhibits Close**

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**Closing Remarks**
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

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
Medical College of Wisconsin Cancer Center

3. Automating Protocol Training Documentation: Regulatory Compliance in a Click
R. Lehman, 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. Hajewski, 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. Krechtib, 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
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, Wayne State University

8. Executing a Healthy Volunteer Study During COVID-19 Pandemic
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

10. 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

11. 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

12. 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
Huntsman Cancer Institute, University of Utah

14. *There and Back Again: A Satellite Site Operations Tale
Huntsman Cancer Institute, University of Utah

15. Establishing an Employee Engagement, Equity, and Education Committee During Remote Operations
J. Feola, M. Kimber, A. Hoeschen, M. Dworak, M. Loza
Masonic Cancer Center, University of Minnesota

16. Transformative Lessons for Clinical Trials From the COVID-19 Pandemic: Remote Monitoring, Virtual Research Visits, and Added Flexibility for Patients
Mayo Clinic Cancer Center

17. Structured Collaboration With Clinical Partners to Enhance Research Participant Safety and Experience Along With Protocol Compliance and Expeditious Trial Activation
S. Willoughby, C. Davis
Robert H. Lurie Comprehensive Cancer Center of Northwestern University

18. 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

*Honorable Mention
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

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

Winship Cancer Institute of Emory University

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

C. Vollmer, T. Herzog, C. Allen, N. Kurtzweil, E. Chandra, B. Hughes  
University of Cincinnati Cancer Center

27. *MSK’s NCI Network Program  
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. Poulandjian  
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. Fernandez, 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. Cicotti, S. Williams, C. Worth  
UNC Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

*Honorable Mention
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

41. 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

44. 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

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
Huntsman Cancer Institute, University of Utah

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

*Honorable Mention
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

61. 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

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

AACI gratefully acknowledges support from the following:

Gold Level

Silver Level

Bronze Level

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AACI gratefully acknowledges support from the following:

**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](http://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](http://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](http://florencehc.com).
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. For more information on nCartes, please visit ncartes.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.

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, AI-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

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

<table>
<thead>
<tr>
<th>Median Overall Survival</th>
<th>FOLFOXai® Indicates:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FOLFOX+BV 1st</td>
</tr>
<tr>
<td></td>
<td>↓ FOLFIRI+BV 2nd</td>
</tr>
<tr>
<td>(FOLFOX+BV RWE cohort)</td>
<td></td>
</tr>
<tr>
<td>OS When Patient Received: FOLFOX+BV 1st</td>
<td>42.0 months</td>
</tr>
<tr>
<td>↓ FOLFIRI+BV 2nd</td>
<td>18.7 months</td>
</tr>
<tr>
<td>OS When Patient Received: FOLFIRI+BV 1st</td>
<td>24.5 months</td>
</tr>
<tr>
<td>↓ FOLFOX+BV 2nd</td>
<td>34.4 months</td>
</tr>
</tbody>
</table>

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.


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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.

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- Development of Analytics / Algorithms
- Data Management
- Omics Analysis
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SOLUTIONS

Atlassian Team Award 2021

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• Ways to Achieve Health Equity in Cancer Research
• Research Priorities That Will Accelerate Progress

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