AACI Association of American Cancer Institutes

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AACI CRI
Clinical Research Innovation

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

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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
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AACI CRI Welcome

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

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

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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

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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

Looking for presentations, exhibitors, or other attendees?
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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

Looking for presentations, exhibitors, or other attendees?
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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, Wayne 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

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**
    J. Espinosa, C. Marshall, A. Horstmeier, J. Moehle, L. Lujan
    Huntsman Cancer Institute, University of Utah

14. ***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

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**
    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

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

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

27. *MSK's NCI Network Program
J. 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

*Honorable Mention

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

2021 Abstracts

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

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
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

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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

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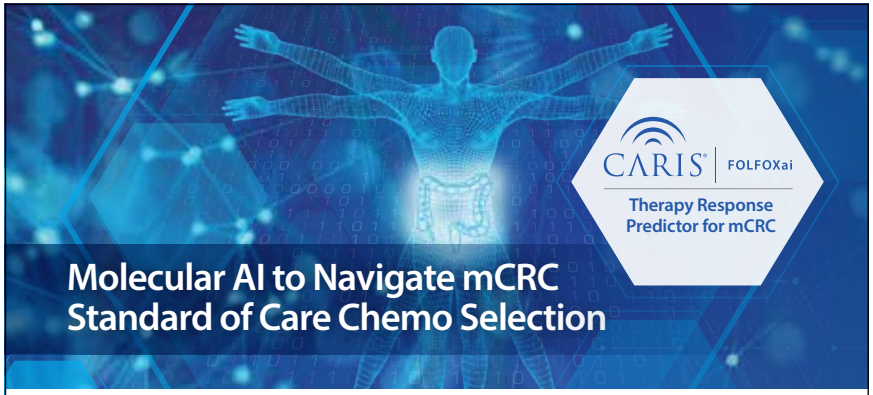

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