

PARTNERING IN PROGRESS



14th Annual AACI CRI Meeting

JULY 12-14, 2022

Loews Chicago O'Hare Hotel

AACI CRI 2022 Steering Committee

Chair: Tara L. Lin, MD

The University of Kansas Cancer Center

Leslie P. Byatt, CCRC, ACRP-PM

University of New Mexico Comprehensive 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

Christopher Loertscher, MA

USC Norris Comprehensive Cancer Center

Patricia M. LoRusso, DO, PhD

Yale Cancer Center, Yale School of Medicine

Eneida Nemecek, MD, MS, MBA

OHSU Knight Cancer Institute

Bhanu Pappu, PhD, MHA

Simmons Comprehensive Cancer Center UT Southwestern Medical Center

Anne Schnatterly, MBA, BSN, RN, CCRP

WVU Cancer Institute

Susanna Sellmann, MRT, BSc., CCRP

Princess Margaret Cancer Centre University Health Network

Rachna Shroff, MD, MS

The University of Arizona Cancer Center

Kate Shumate, MPA, CCRP

UCSF Helen Diller Family Comprehensive Cancer Center

Meeting App and Social Media

The agenda, presentations, exhibitor information, and attendees list are available on the meeting app.

To access the app:

- Download "Cvent Events" from your mobile app store.
- Log in with the name and email used during registration.
- You will receive a 6-digit verification code. Enter your code and log in.
- Within the Cvent Events app, search for "14th Annual AACI Clinical Research Innovation Meeting" and download the meeting.

The meeting app can also be accessed on your desktop at: https://cvent.me/NQV48v

Twitter: @AACI_Cancer Facebook: AACICancer Hashtag: #CRI2022

Wireless Network: AACI CRI Wi-Fi

Password: 2022cri

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 (CTO) at AACI cancer centers.

The programming of the 14th Annual AACI CRI Meeting, "Partnering in Progress," aligns with CRI's strategic goal of stimulating cancer center interactions to maximize resources by creating opportunities for peer-to-peer networking and collaboration.

2022 Strategic Plan & Goals

- 1. Increase AACI cancer center participation in CRI
- Collect and disseminate benchmarking data to develop cancer center clinical trial best practices
- 3. Integrate CRI into AACI programs and initiatives
- 4. Assist cancer centers in improving community outreach and engagement to increase enrollment in clinical trials
- 5. Promote diversity, equity, and inclusion for training and career development
- 6. Develop clinical research education and resources for professional development
- 7. Increase engagement with industry and other stakeholders to support CRI
- 8. Develop outcomes to drive change and advance cancer center clinical research programs
- 9. Create a network for leadership to continue fostering communication and mentoring opportunities

AACI CRI Meeting Objectives

- Offer an industry perspective on diversity related to the workplace and clinical trial recruitment
- Address how cancer centers utilize their institutional support to broaden a culture of diversity, equity, and inclusion (DEI)
- Share strategies that CTOs are using to engage research team collaboration with community outreach and engagement (COE) "champions" and the benefits of working with community liaisons or navigators to increase trial enrollment
- Discuss ways to provide community patients access to research drugs and improve the research treatment experience using community-based navigators, home health care, and telehealth
- Share successful recruitment models for rapid onboarding of staff to address the unprecedented employee shortages resulting from the "Great Resignation"
- Discuss the expanding use of innovative technology to enhance staff efficiency and patient experience in clinical trials
- Review the advantages of using a clinical trial feasibility process to ensure a realistic assessment of trial site capabilities for conducting trials
- Learn the benefits of rightsizing clinical trial portfolios for streamlining CTO operations while addressing staffing gaps to improve patient outcomes
- Review the practical implications of preparing a National Cancer Institute (NCI)
 Cancer Center Support Grant competing renewal, with a focus on the Clinical
 Trials Reporting Program, revisions to the Funding Opportunity Announcement,
 and the funding of investigator-initiated trials
- Understand cancer center catchment areas, the NCI's new diversity and inclusion reporting requirements, and prospects for continued virtual site visits

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

14th Annual AACI Clinical Research Innovation Meeting

Tuesday, July 12 – Thursday, July 14

Tuesday, July 12

10:00 AM Registration Opens Artist Foyer

12:00 PM Exhibits Open Artist Foyer

12:00 PM Welcome Cassatt Ballroom

Tara L. Lin, MD

The University of Kansas Cancer Center

12:30 PM Supporting a Culture of Diversity, Equity, and Inclusion Cassatt Ballroom

Diversity, equity, and inclusion (DEI) programming is becoming increasingly common across industries, but successful implementation requires institutional support. Discussion will cover strategies for broadening DEI efforts within cancer centers.

Moderator: Eneida Nemecek, MD, MS, MBA

OHSU Knight Cancer Institute

Narjust Florez, MD

Dana-Farber Cancer Institute. Harvard Medical School

Meredith Russell, CCRP

University of Illinois Cancer Center

Jaszianne Tolbert, MD

Janssen

1:30 PM Function-Based Breakout Sessions

Clinical Trials Office Leadership Louvre 1

CTO medical directors and administrative directors will discuss policies for reducing staff turnover, ways to increase staff engagement in remote or hybrid work environments, and metrics to support remote work.

Data Management Pollock

Breakout session participants will discuss research data collection using source documents and the hospital's EMR. Other topics include the challenges of working with various clinical trial management applications provided by trial sponsors, developing metrics for timely data entry and quality assurance, managing remote and site monitoring visits, and managing data queries.

Management and Program Management Warhol

In this breakout session, managers will discuss how to effectively motivate and communicate with staff to balance workloads, increase productivity and efficiency, and maintain a positive environment.

Regulatory Management Avedon A

Breakout session participants will share best practices for creating and maintaining the clinical trial regulatory file and electronic systems to reduce paper and increase efficiency. Participants will also discuss working with regulatory bodies, the U.S. Food and Drug Administration, and local and central institutional review boards; continuing renewals; and managing trial closures.

Trial Coordination Avedon B

Participants in this breakout session will describe best practices for coordination of clinical trials to include methods for screening and consenting patients, confirming trial eligibility, coordinating protocol procedures and investigational drug ordering, reporting serious adverse events, and documenting sources in the electronic medical record.

Trial Start-up Louvre 2

Trial activation involves teamwork from people in various roles, working both inside and outside the clinical trials office. Breakout participants will discuss challenges and methods for shrinking the trial activation timeline while working with the cancer center's protocol and review monitoring system to prioritize trials. Other topics include coordinating workflows for developing trial budgets, negotiating contracts, and developing Medicare coverage analysis.

2:30 PM **Networking Break** Artist Fover

Supported by Essex Management

3:00 PM Clarity and Perspective: The NCI Cancer Center **Support Grant and New Reporting Guidelines**

Cassatt Ballroom

National Cancer Institute (NCI) officials will provide an overview of recent and proposed changes to NCI's Cancer Center Support Grant (CCSG), including new guidelines for reporting data for pragmatic trials. Panelists will also review the practical implications of preparing a CCSG competing renewal, with a focus on the Clinical Trials Reporting Program, revisions to the Funding Opportunity Announcement including funding of investigator-initiated trials and catchment area considerations—new diversity and inclusion reporting requirements, and prospects for continued virtual site visits.

Moderator: Kate Shumate, MPA, CCRP UCSF Helen Diller Family Comprehensive Cancer Center

Krzysztof Ptak, PhD National Cancer Institute

4:00 PM Poster Session Avedon CD

Welcome Reception Artist Fover 5:30 -

6:30 PM Supported by Florence

Wednesday, July 13

7:00 AM General Breakfast Guggenheim Ballroom – Museum Wing

7:00 AM **CTO Administrative Directors' Breakfast**

(invitation only) Prado 1

7:00 AM **CTO Medical Directors' Breakfast** (invitation only)

Prado 2

8:00 AM **Exhibits Open** Artist Foyer

8:15 AM **Welcome** Cassatt Ballroom

Tara L. Lin, MD

The University of Kansas Cancer Center

8:30 AM **Keynote Presentation: Optimizing Diversity Efforts** Cassatt Ballroom

Bristol Myers Squibb People and Business Group Lead Monique Phillips, PMP, will offer an industry perspective on diversity – both as it relates to workplace culture and to clinical trial recruitment. She will be joined in discussion by ovarian cancer survivor and patient advocate Kimberly Richardson, of Black Cancer Collaborative. Topics will include patient navigation; implicit bias; outreach and education strategies; and diversity, equity, and inclusion programs.

Monique Phillips, PMP

Bristol Myers Squibb

Kimberly Richardson

Black Cancer Collaborative

9:30 AM **Meeting Our Patients on Their Terms** Cassatt Ballroom

Panelists will discuss ways to improve the treatment experience for patients, including the use of community-based navigators and drug shipments to affiliate sites. Additionally, a patient advocate will share their unique perspective.

Moderator: Bhanu Pappu, PhD, MHA

Simmons Comprehensive Cancer Center, UT Southwestern Medical Center

Sean DeFrates, PharmD

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

Annie Ellis

Memorial Sloan Kettering Cancer Center

Fabian Robles, MSc-HLM

Simmons Comprehensive Cancer Center, UT Southwestern Medical Center 5

10:30 AM Break

10:45 AM Using Technology to Simplify CTO Administrative Responsibilities Cassatt Ballroom

Supported by Veeva

Artificial intelligence innovations such as automated trial-patient matching and other technology solutions (e.g., electronic informed consent and electronic regulatory management systems) are enhancing clinical trials office efforts to reduce administrative burden on staff that are sometimes overwhelmed by the shifting workplace demands caused by the ongoing COVID-19 pandemic. This panel discussion will explore the expanding use of technology to enhance both staff efficiency and patient experience in clinical trials.

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

Tricia Bentz, MHA, CCRP

Hollings Cancer Center, Medical University of South Carolina

Jocelyn Brown, CCRP

Stephenson Cancer Center, University of Oklahoma

Ashley Drawz, MSRC, CCRC

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

11:45 AM Lunch Guggenheim Ballroom – Museum Wing

12:45 PM Ensuring a Good Study: The Clinical Trial Feasibility Process Cassatt Ballroom

A rigorous clinical trial feasibility process helps to ensure a realistic assessment of your ability to conduct the trial. Panelists in this session will examine steps in the process such as assessing internal and environmental capacity, aligning the clinical trial with study design, and evaluating the timing and other logistics of opening a trial at an affiliate site. Pharmacy considerations like investigational drug availability and dosage will also be discussed along with approaches to interfacing with a cancer center's protocol review and monitoring committee.

Moderator: Leslie P. Byatt, CCRC, ACRP-PM

University of New Mexico Comprehensive Cancer Center

Frances Brogan, MSN, RN, OCN, CCRP

Herbert Irving Comprehensive Cancer Center Columbia University Irving Medical Center

Donna Katz, MSN, APRN, FNP-BC, OCN UCLA Jonsson Comprehensive Cancer Center

Brian Miller, PharmD

UPMC Hillman Cancer Center

1:45 PM Topic-Based Breakout Sessions

Trial Activation Outside the Clinical Trials Office (CTO) Warhol

Trial activation requires the teamwork of members both within and outside the CTO. Breakout session participants will discuss their methods for working with their finance and contracts teams and sponsors to activate trials within required timelines and meet trial budget requirements.

Managing Trials From Beginning to End *Louvre 3*

Session participants will discuss rightsizing your clinical trial portfolio in the current environment to address your cancer patients' needs and maintain CTO efficiency.

Shared Investigator Platform (SIP) Avedon B

Breakout session participants will describe the challenges with SIP adoption and trial activation. Topics include site facility setup, establishing investigator profiles, and staffing the site administrator role. Representatives from Cognizant will be available to answer questions.

Reviewing Investigator-Initiated Trials With Your Data Safety Monitoring Committee *Pollock*

Participants in this breakout session will discuss how they work with their Data Safety Monitoring Committee to review safety reports and monitor investigator-initiated trials.

Managing Multisite Investigator-Initiated Trials (IIT) Louvre 1 Participants will discuss the management of multisite IITs and best

practices for providing investigational drugs and managing the regulatory file.

Managing Your Community Trial Sites Avedon A

Breakout session participants will discuss trial site selection, trial monitoring, and ensuring timely and accurate data collection. They will also address financial considerations for sites working with trial site affiliates.

Diversity, Equity, and Inclusion: Working With Your COE *Louvre 2*

Participants will continue the conversation on methods for engaging the community. Discussion may include working with community navigators and patient advocates; determining how to diversify and retain staff; and enrolling more patients in clinical trials.

2:45 PM Networking and Dessert Break Artist Foyer

Supported by Advarra

3:15 PM 2022 CRI Abstract Presentations Cassatt Ballroom

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. The abstract presentations will be followed by a Q&A session.

Moderator: Tara L. Lin, MD

The University of Kansas Cancer Center

Angela Fritsche, MPA

Mayo Clinic Comprehensive Cancer Center

Erin Hastings Monari, PhD, CCRP

University of Florida Health Cancer Center

Josefina Sanchez, CCRC

Sylvester Comprehensive Cancer Center University of Miami Health System

4:15 PM Honorable Mention Poster Session Cassatt Ballroom

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

Moderator: Tara L. Lin, MD

The University of Kansas Cancer Center

Christina Crabtree-Ide, PhD, MPH

Roswell Park Comprehensive Cancer Center

Theresa Cummings, RN, DBA, CCRP

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

Emily Hautamaki, RN, MPH, CCRP

Cedars-Sinai Cancer

Ashley McCauley, MA, CCRP

Fred Hutchinson Cancer Center

Justin Miller

The Tisch Cancer Institute at Mount Sinai

Lillian Neal, MSc, CCRP

Hollings Cancer Center, Medical University of South Carolina

Renata Panchal, MS

Memorial Sloan Kettering Cancer Center

Beth Scanlan, MAP, CCRP

UAMS Winthrop P. Rockefeller Cancer Institute

5:15 PM Vendor Presentation: Advarra

Site-Sponsor Consortium: Connecting Research Sites and Sponsors Through an Integrated Technology Ecosystem

In this session, Laura Hilty, vice president, strategy at Advarra, will outline the challenges and present solutions for cancer centers overburdened by sponsor-driven technology. Hilty will share metrics from a recent survey conducted by Advarra and Society for Clinical Research Sites and will highlight progress made by a new consortium of sites, sponsors, and clinical research organizations. The consortium is working together to connect existing site technology to sponsor systems seamlessly, addressing the duplicative efforts, longer timelines, and reduced patient focus often associated with sponsor-provided technology. Hilty will showcase progress made by Advarra as a result of the consortium's efforts and provide actionable insight for attendees to take advantage of this connected ecosystem, empowering site stakeholders to drive efficiencies across the clinical trial lifecycle.

8:00 – 10:00 PM Hospitality Ice Bar, Lobby Level

Supported by WellSky

Thursday, July 14

7:00 AM Breakfast Guggenheim Ballroom – Museum Wing

8:00 AM Exhibits Open Artist Foyer

8:00 AM Welcome Cassatt Ballroom

Theresa L. Werner, MD

Huntsman Cancer Institute, University of Utah

8:15 AM Integrating the CTO With Community Outreach and Engagement Cassatt Ballroom

Combining the work of a cancer center's clinical trials office with its community outreach and engagement (COE) efforts can result in increased trial enrollment and improved community engagement. Panelists will share strategies, including research team collaboration with COE "champions" and the benefits of working with community liaisons or navigators. The results of a recent CRI diversity survey will also be shared.

Moderator: Rachna Shroff, MD, MS University of Arizona Cancer Center

Rhoda Arzoomanian, MSM, RN, BSN City of Hope Comprehensive Cancer Center

Debbie Chatman Bryant, DNP, RN, FAAN

VCU Massey Cancer Center

Timothy Rebbeck, PhD

Dana-Farber Cancer Institute, Harvard Medical School

Andrew Sussman, PhD, MCRP

University of New Mexico Comprehensive Cancer Center

9:15 AM Rightsizing the Clinical Trial Portfolio Cassatt Ballroom

Much as a quarterly review of financial investments helps to generate income and minimize losses, a clear-eyed analysis of a clinical trial portfolio can streamline CTO operations and improve research and patient outcomes. Helping disease teams prioritize staffing, closing trials, increasing trial efficiency numbers, and focusing on the National Cancer Institute's Cancer Center Support Grant requirements, especially as they relate to investigator-initiated trials, are some of the steps toward rightsizing a clinical trial portfolio that will be examined in this session.

Moderator: Anne Schnatterly, MBA, BSN, RN, CCRP

WVU Cancer Institute

Michael Pearl, MD

Stony Brook Cancer Center

Theresa Sberna, MPH

Vanderbilt-Ingram Cancer Center

10:15 AM Break

10:30 AM Successful Staff Retention and Training

Cassatt Ballroom

Amid the "Great Resignation" and unprecedented staffing shortages, recruiting, training, and retaining employees have become top priorities among cancer centers. Speakers will share successful recruitment strategies and models for rapid onboarding. They will also address rightsizing trial portfolios and maintaining trial accruals despite staffing gaps.

Moderator: Christopher Loertscher, MA

USC Norris Comprehensive Cancer Center

Chloe Fournier, MBA, CCRP

Duke Cancer Institute, Duke University Medical Center

Stacey Lewis, RN, BSN, OCN, BBA

Atrium Health Wake Forest Baptist Comprehensive Cancer Center

Andrea Skafel, MSc, CCRP

UCSF Helen Diller Family Comprehensive Cancer Center

11:30 AM Closing Remarks Cassatt Ballroom

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

11:45 AM Adjourn

AACI CRI Meeting 2022 Abstracts

FIRST PLACE:

5. Successful Methods of Addressing Clinical Research Staff Turnover

N. Nahmias, J. Sanchez, A. Olier-Pino, A. Allred, K. Aviles, L. Corrales

Sylvester Comprehensive Cancer Center, University of Miami Health System

SECOND PLACE:

32. Starting Off on the Right Foot: Elevating the Voice of Community Stakeholders During the IIT Development Process

E. Monari, S. Szurek, A. Ivey, T. George, A. Anderson, E. Shenkman, C. Evans, A. Lawson-Ross

University of Florida Health Cancer Center

THIRD PLACE:

8. Clinical Research Coordinator Workload Estimation and Tracking

M. Repede, D. Beighley, K. Putz, A. Fritsche, G. Nowakowski

Mayo Clinic Comprehensive Cancer Center

Abstracts are organized by category and completion status, then in alphabetical order by cancer center.

Clinical Trial Operations

 Clinical Trial Office Response to COVID-19 at an Academic Comprehensive Cancer Center

E. Bentlyewski, F. Brogan, R. Shelton, J. Jurcic, A. Lassman

Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center

2. CTO Benchmarking Study

M. Contreraz, T. Lautenschlaeger, K. Lee, K. Miller, B. Hicks, A. Sands, F. Bhimani, M. Gee, T. Hanson, B. Richardson

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

3. Single Institution Experience of Integrating Radiation Oncology Clinical Research Into Comprehensive Cancer Center CTO

T. Lautenschlaeger, M. Contreraz, L. Rohn, T. Glendenning, L. Vaughn, R. Zellars, K. Lee, K. Miller

Indiana University Melvin and Bren Simon Comprehensive Cancer Center

4. Solutions for Clinical Research Continuity During the COVID-19 Pandemic

N. Nahmias, J. Sanchez, A. Olier-Pino, A. Allred, K. Aviles, L. Corrales Sylvester Comprehensive Cancer Center, University of Miami Health System

 Successful Methods of Addressing Clinical Research Staff Turnover N. Nahmias, J. Sanchez, A. Olier-Pino, A. Allred, K. Aviles, L. Corrales Sylvester Comprehensive Cancer Center, University of Miami Health System

6. eRegulatory Process and Software Implementation in Times of Crisis J. Stern, R. Jones, C. Henrichs

Vanderbilt-Ingram Cancer Center

 Automated Reporting for Clinical Trial Operations M. Rump, M. Kilbane, K. McCaffrey, B. Matia, J. Lindberg Cleveland Clinic Cancer Center

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8. Clinical Research Coordinator Workload Estimation and Tracking M. Repede, D. Beighley, K. Putz, A. Fritsche, G. Nowakowski Mayo Clinic Comprehensive Cancer Center

9. Data Automation to CIBMTR C. Thomas, R. Panchal, J. Konecny, T. Casali

Memorial Sloan Kettering Cancer Center

10. Memorial Sloan Kettering Cancer Alliance's Cancer Control and Population Science Subcommittee

S. Yoon

Memorial Sloan Kettering Cancer Center

11. Data Talks: Using Non-Compliance Tracking to Improve Patient Safety E. Harms, N. Borror, E. Menne

Siteman Cancer Center

12. Digital Transformation of Sylvester Comprehensive Cancer Center Research Lab: A Work in Progress

P. Seo, A. Bivin-Martinez, J. Trent

Sylvester Comprehensive Cancer Center, University of Miami Health System

13.*Implementing "Protected Time" to Increase Clinical Research Coordinator Data Entry Efficiency

J. Miller, S. Scheiner, C. Varnadoe-Rothman, S. Lopiano, N. Taylor, P. Garcia The Tisch Cancer Institute at Mount Sinai

14. Study Start-up Dashboard

D. Mudaranhakam, S. Pepper, A. Tribitt

The University of Kansas Cancer Center

15. Establishing a Pre-Screening Process – Creating the Right Tool

S. Panozzo, T. Prichett, B. Carter, K. Allen, D. Steward, M. McAdoo, R. Dooley, K. Smith, L. Cunningham, Z. Feng, A. Smith, M. Birrer

UAMS Winthrop P. Rockefeller Cancer Institute

Information Technology Research Systems, University of Arkansas for Medical Sciences

Navigating Oncology Clinical Trials in the Era of COVID-19 – A CRC Perspective

M. Boota, K. Allen, S. Panozzo, M. Kovak, M. Birrer UAMS Winthrop P. Rockefeller Cancer Institute

17. Microsoft Power Platform: Improving Efficiency, Communication, and Documentation in the Clinical Research Setting

M. Fritz, J. Plassmeyer, M. Horak, T. Cronauer (Horne), S. Perry, J. Griffo, D. Cleary UPMC Hillman Cancer Center

18. Surveying Staff Satisfaction to Work Toward Improved Employee Retention

J. Binder, D. Ritter, K. Garcea, M. Fritz, M. Horak, D. Cleary
UPMC Hillman Cancer Center

2022 Abstracts

Finance/CCSG/PRMS

 Creation of a Consort Diagram to Visualize Participant Enrollment and Allocation at the Memorial Sloan Kettering Data and Safety Monitoring Committee

C. Kolenut, K. Napolitano, X. Lekperic, S. Hanley, K. Tan, E. O'Reilly, S. Slovin Memorial Sloan Kettering Cancer Center

20. Research Portfolio Management: The Protocol Performance Monitoring Dashboard

J. Migliacci, X. Lekperic, B. Seko, K. Kaufman, K. Napolitano, S. Hanley, A. Rodavitch Memorial Sloan Kettering Cancer Center

21. PRMC Member Workload Survey After Charter Alignment With NCI Requirements

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

22. Impact of the SRMC Zero Tolerance Policy on DSG Trial Portfolios

J. Walsh, T. Guinn, Jr., T. George, A. Anderson, A. Ivey University of Florida Health Cancer Center

23.*Taking a Closer Look: Standardizing Disease Focus Groups to Strengthen Trial Portfolios

L. Neal

Hollings Cancer Center, Medical University of South Carolina

24. Automating and Streamlining the 2-Stage Scientific Review Process

T. Baxter, J. Welter, M. Voss, M. Golafshar, T. DeWees, J. Clikeman, A. Fritsche,

J. Summer Bolster, A. Dispenzieri

Mayo Clinic Comprehensive Cancer Center

25. Clinical Research: Following the Money Phase III

R. Geary, P. Eggleton, M. Kovak, M. Birrer, A. Smith, Z. Feng, N. Pruss

UAMS Winthrop P. Rockefeller Cancer Institute

Information Technology Research Systems, University of Arkansas for Medical Sciences

26. Monitoring Study Enrollment Demographics: PRMS-COE Collaboration at University of Colorado Cancer Center (UCCC)

D. McCollister, D. Pacheco, A. Henningham, E. Borrayo, C. Cost

University of Colorado Cancer Center

Investigator-Initiated Trials

27.*Development of a Multisite Investigator-Initiated Trial Coordinating Center at Cedars-Sinai Cancer

E. Hautamaki, D. Ngo, A. Tan, P. Chang

Cedars-Sinai Cancer

28. Development of a Workload Assessment Tool for Investigator-Initiated Trial Protocol Development Based on the Ontario Protocol Assessment Level Scale

E. Hautamaki

Cedars-Sinai Cancer

29. Building IND Infrastructure to Ensure Compliance and Enable Growth

J. Morrison, N. Babadi, E. Crecelius, S. Scott, R. Johnson, S. Boyle, M. Retter, A. Camp,

L. Kiefer, C. Lee

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

30. Development of an Investigator-Initiated Trial Intake Process at Cedars-Sinai Cancer

E. Hautamaki, P. Chang, D. Ngo, A. Tan

Cedars-Sinai Cancer

31. Streamlining Data Collection: Implementation of an EDC FHIR Lab Interface

E. Crecelius, M. O'Dwyer, L. Logan, S. Balu, J. Frank, R. Johnson, R. Church, C. Lee,

J. Morrison

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

32. Starting Off on the Right Foot: Elevating the Voice of Community Stakeholders During the IIT Development Process

E. Monari, S. Szurek, A. Ivey, T. George, A. Anderson, E. Shenkman, C. Evans,

A. Lawson-Ross

University of Florida Health Cancer Center

33. UF's IIT Think Tank Experiment

E. Monari, A. Ivey, T. George, A. Anderson

University of Florida Health Cancer Center

Quality Assurance, Remote Monitoring, and Auditing

34. Proactive Quality Assurance Through Dual Review of Eligibility and Consent

K. Thorne

Huntsman Cancer Institute, University of Utah

35. Transforming Risk Management: Technological Evolution of MSK's Clinical Research Quality Assurance Program

A. Granobles, M. Satter, S. Puleio, F. Puma, N. Brosnan, K. Yataghene

Memorial Sloan Kettering Cancer Center

36.*Virtual Monitoring and Auditing Digitization in Decentralized Clinical Trials: Source Document Verification, System Scheduling, and Real Time Protocol Performance Feedback

M. Buckley, J. Lengfellner, M. Latif, K. Yataghene, C. Houston, S. Terzulli, N. Cimaglia, P. Sabbatini

Memorial Sloan Kettering Cancer Center

2022 Abstracts

37. Automating Data Safety Monitoring Committee (DSMC) Progress Reports

T. McSpadden, S. Grolnic

University of Colorado Cancer Center

38. Introducing a Quality Management System Into the Mayo Clinic Cancer **Center Clinical Research Office**

K. Alexander, K. Croghan, A. Fritsche, J. Summer Bolster, J. Welter Mayo Clinic Comprehensive Cancer Center

39. Preparing and Sharing Subject Cases for Remote NCTN Audit

K. Rygalski, M. Russell, D. Kitterman

University of Illinois Cancer Center

40. Standardized Quality Metrics in Cancer Clinical Trials:

A Qualitative Study

H.A. Forbes McClellan, A. Anglemyer, E. Davis, A. Dumont, K. Shaddox, R. Simons, J. Stern

Vanderbilt-Ingram Cancer Center

Regulatory

41. Digitalizing and Automating Clinical Research Protocol Regulatory **Binders for Greater Efficiencies**

M. Buckley, R. Lehrman, J. Lengfellner, M. Latif, K. Yataghene, C. Houston, S. Terzulli, P. Sabbatini

Memorial Sloan Kettering Cancer Center

42.*Delegation of Authority - A Simplified Process

B. Scanlan, A. Holley, M. Kovak, B. Lehman, P. Newman, R. Perry, D. Wade, M. Birrer UAMS Winthrop P. Rockefeller Cancer Institute

43. Optimization of a Regulatory eBinder Platform

S. Rebar, K. Lopez, D. Cervantes

Fred Hutchinson Cancer Center

44. Simplifying and Improving Training and Delegation Documentation R. Kingsford, L. Hayes, L. Lujan

Huntsman Cancer Institute. University of Utah

45. Supporting Virtual Clinical Trials: How the Generation of DOAs in PIMS Has Enabled Clinical Trial Compliance in a Remote World

P. Lim

Memorial Sloan Kettering Cancer Center

Training and Career Development

46. Investing in Investigator Training: Developing Tools to Close the Gap L. Valanejad Kiefer, N. H. Babadi, M. Robinson, A. Camp, C. Lee, J. K. Morrison

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

47. The Effectiveness of an Innovative Competency-Based Education and Training Program on Decreasing Audit Findings

E. Dawkins, S. Cole, N. Nahimas, P. Seo, and J. Brown

Sylvester Comprehensive Cancer Center, University of Miami Health System

48. Comprehensive Application of Supplemental Phantom Educational Resources (CASPER): a Friendly Phantom Patient to Guide the Way for New Study Coordinators

E. Cunningham, L. Dunham, B. Olsen

Karmanos Cancer Institute, Wayne State University

49. Implementation of Small Group Trainings to Expedite Initial Onboarding for Clinical Research Staff and Increase Connection Between New Employees

D. Kreitner, M. Wanchoo, D. Castro, C. Burgin

OHSU Knight Cancer Institute

50.*Staffing Pipeline Creation: Clinical Research Internship for Undergraduate BIPOC Students

T. Cummings, A. Walens, A. Leak-Bryant, V. Carlisle, M. Haines, C. Lee

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

51. Using Surveys to Evaluate Staff Onboarding Experiences: Pandemic to Present

C.L. Allen, P. Rose, M. Marcum, N. Kurtzweil

University of Cincinnati Cancer Center

52. Piloting a New Investigator E-Learning Onboarding Program

J. Thomas, M. Murphy, T. George, A. Anderson, E. Monari, A. Ivey

University of Florida Health Cancer Center

Trial Recruitment & Community Outreach and Engagement

53. Community Outreach, Community of Color Accrual: CS-Link Registration and OnCore Enhancements to Capture Ethnic Subgroups, Gender, and Sexual Orientation

J. Gomez, B. Rimel

Cedars-Sinai Cancer

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- 65. It's About Time: A Simplified Approach to NCI Trial Activation J. Balletti, L. Gaffney, M. Warren, S. Hanley, E. Valentino, A. Rodavitch, J. Migliacci Memorial Sloan Kettering Cancer Center
- 66. Strategies to Expedite Activation of Expanded Access Protocols at **Memorial Sloan Kettering Cancer Center** X. Lekperic, E. Valentino, S. Hanley, A. Rodavitch

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- 69. Clinical Trial Research Group (CTRG) Guidelines for Trial Portfolio Management
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- 70. Technology and Centralization in Early Study Start-up Activities E. Lebleu, L. Lujan, J. Moehle, T. Werner Huntsman Cancer Institute, University of Utah
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72. Improving Trial Activation Timelines: A Comprehensive Process **Improvement Project**

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73. Value Stream Mapping: Maximizing Value, Minimizing Waste, and Improving Flow Across the Clinical Trial Activation Process P. Arlen, L. Thyssen, K. Williams

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74. Implementation of a Feasibility Committee – University of Cincinnati **Cancer Center (UCCC) Study Operations & Administrative Review** (SOAR)

A. Kastl, M. Marcum

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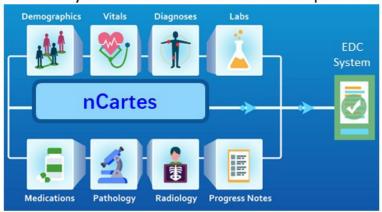
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