

**CANCER CLINICAL RESEARCH
FOCUS ON THE FUTURE**

**12th Annual Meeting
July 7-8, 2020**

AACI
Association of
American
Cancer Institutes

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

Phone: 412-647-6111

www.aaci-cancer.org

AACI CRI 2020 Steering Committee

Chair - Theresa L. Werner, MD

Huntsman Cancer Institute, University of Utah

Tricia Adrales Bentz, MHA, CCRP

Hollings Cancer Center
Medical University of South Carolina

Stefan C. Grant, MD, JD, MBA

Wake Forest Baptist Comprehensive Cancer Center

Janie Hofacker, RN, BSN, MS

Association of American Cancer Institutes

Collette M. Houston

Memorial Sloan Kettering Cancer Center

Tara L. Lin, MD

The University of Kansas Cancer Center

Melissa Anne Nashawati, MPA

Mays Cancer Center, UT Health San Antonio

Bhanu Pappu, PhD, MHA

UPMC Hillman Cancer Center

Helen Peck, RN, MA, OCN, CCRP

Wilmot Cancer Institute, UR Medicine

Jessica Rhee, MD, MS

University of Hawai'i Cancer Center
University of Hawai'i at Mānoa

Michael Sainz

Dartmouth-Hitchcock Norris Cotton Cancer Center

Alex Zafirovski, MBA

Robert H. Lurie Comprehensive Cancer Center of
Northwestern University

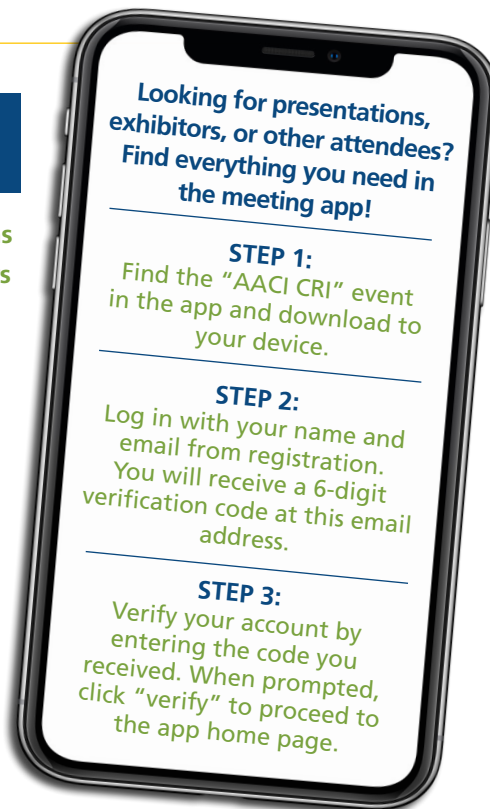
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Twitter: @AACI_Cancer

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Hashtag: #CRI2020



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AACI CRI Welcome

With more than a decade of consistent growth, the Association of American Cancer Institutes (AACI) Clinical Research Innovation (CRI) program has expanded from an initiative into a permanent fixture among cancer center clinical trials professionals. CRI's forward momentum also drives the programming of the 12th Annual AACI CRI Meeting, titled "Cancer Clinical Research: Focus on the Future." The CRI annual meeting program aligns with AACI's strategic goal of stimulating cancer center interactions to maximize resources by creating opportunities for peer-to-peer networking and collaboration. CRI participants fill a variety of leadership roles and possess a comprehensive understanding of the clinical trials system.

CRI Strategic Plan Goals

1. Increase AACI cancer center participation in CRI
2. Share cancer center clinical trial best practices through the collection and dissemination of benchmarking data
3. Integrate CRI into AACI programs/initiatives
4. Assist the centers in increasing patient engagement and enrollment 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

- Utilize novel technologies, including telemedicine and wearables, to improve cancer clinical trial efficiency and bring more trials to remote or rural sites
- Understand how generational differences impact the clinical trials office (CTO) workforce and capitalize on diverse strengths to build a stable research program
- Apply change management principles to CTOs to encourage innovation, productivity, flexibility, and accountability
- Apply an understanding of the National Cancer Institute (NCI) Cancer Center Support Grant to set clinical research priorities and prepare for a virtual site visit

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

12th Annual AACI Clinical Research Innovation Meeting

Tuesday, July 7 – Wednesday, July 8 | **Virtual Meeting**

All session times are in Eastern Daylight Time.

Tuesday, July 7

10:00 AM Exhibits Open

10:00 AM Abstracts Open

11:00 AM Welcome

Theresa L. Werner, MD

Huntsman Cancer Institute, University of Utah

A Message From Florence

11:10 AM Harnessing Technology to Allow Your CTO to Work Remotely

Brought to you by Florence

Choosing the right information technology—and successfully implementing it—can be daunting in the best of times. In recent months, clinical trials offices have had to respond and adapt to a public health emergency using the technology available to them. Panelists will discuss how electronic signatures, eConsent, remote monitoring, wearables, eRegulatory platforms, telemedicine, and other tools have improved their cancer centers' clinical trials operations in a rapidly changing environment.

Moderator: Collette M. Houston

Memorial Sloan Kettering Cancer Center

Muhammad Beg, MD

*Simmons Comprehensive Cancer Center,
UT Southwestern Medical Center*

Theresa Cummings, RN, MS, CCRP

*University of Maryland
Marlene and Stewart Greenebaum Comprehensive Cancer Center*

Leslie Pettiford, RN, MS, OCN, CCRC

University of Florida Health Cancer Center

A Message From Veeva Systems

12:15 PM Managing Change in Clinical Trials Offices

The COVID-19 pandemic is dramatically altering who we work with and how we do it. Consequently, resilience is essential. Panelists will highlight successful strategies for managing and facilitating change in clinical trials offices, including maximizing staff retention by creating a work environment that offers flexibility without sacrificing accountability, productivity, and quality.

Moderator: Michael Sainz

Dartmouth-Hitchcock Norris Cotton Cancer Center

Kimberly Jenkins, MSNM

Cleveland Clinic Cancer Center

Stefanie Belanger, CCRP

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

Andrea Skafel, MSc, CCRP

UCSF Helen Diller Family Comprehensive Cancer Center

1:20 PM Break Sponsored by Essex Management

1:35 PM Keynote Presentation: Zap the Generational Gap

For the first time in history, there are five generations working side by side. Each generation has been influenced by the major historical events, social trends, and cultural phenomena of their time. Consequently, each has different values, standards of quality, and attitudes toward customers and coworkers. In this highly-charged, participatory presentation, generational humorist Meagan Johnson will outline the dominant generational forces in the workplace and how each generation's "signpost" drives motivation and influences company loyalty, delivery of customer service, and communication between coworkers.

Meagan Johnson

Johnson Training Group

2:40 PM Building a Foundation to Thrive in the New Clinical Research Landscape

Vendor Presentation: Advarra, home of Forte Technology Solutions

Over the span of just a few months, clinical research has changed dramatically. The industry is adapting to the challenges brought on by COVID-19 and must continue to evolve in an increasingly remote environment. Advarra leadership will provide an overview of the current state of clinical research, where the industry is headed, and how you can set your institution up for success. Advarra-Forte customers and AACI members will share their successes using technology to keep research moving during the pandemic and ensure stability in the post-COVID landscape.

Jivan Achreja

Advarra

3:10 PM Adjourn

Wednesday, July 8

10:00 AM Exhibits Open

11:00 AM Welcome

Theresa L. Werner, MD

Huntsman Cancer Institute, University of Utah

11:10 AM 2020 CRI Abstract Presentations

AACI cancer center abstracts focus on oncology 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.

Moderator: Theresa L. Werner, MD

Huntsman Cancer Institute, University of Utah

FIRST PLACE

Standardized and Personalized Training Results in Increased Job Satisfaction and a Reduction in Turnover

K. Jenkins, J. Workman, L. Mooney, M. Kilbane

Cleveland Clinic Cancer Center

SECOND PLACE

The Challenges and Successes of Enrolling Participants on the Tomosynthesis Mammographic Imaging Screening Trial (TMIST or study EA1151) in Hawaii's Minority/Underserved NCI Community Oncology Research Program (M/U NCORP)
S. Cheng¹, S. Wakuk¹, S. Lieu¹, N. Ramos¹, K. Bryant-Greenwood¹, K. Cassel¹, J. Berenberg¹, M. Ka'aihue², R. Lee², E. Capps²

¹University of Hawai'i Cancer Center, University of Hawai'i at Manoa;

²Queen's Medical Center

THIRD PLACE

Enhancing Productivity: Utilizing the ONBASE Application and Pharmacist Created Order Sets to Streamline the Trial Launch Process

B. Secor, I. Reveles, D. Yzquierdo, A. Rodriguez, M. Nashawati, M. Tomasini, P. Manea

Mays Cancer Center, UT Health San Antonio

12:15 PM Poster Session

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

Moderator: Theresa L. Werner, MD

Huntsman Cancer Institute, University of Utah

Ryan Chiechi, MBA

City of Hope Comprehensive Cancer Center

Tiffany Cull, CIP, CCRP

University of Colorado Cancer Center

Maureen Kelley, MS, CCRP

Barbara Ann Karmanos Cancer Institute, Wayne State University

Rachel Kingsford, MS, CCR

Huntsman Cancer Institute, University of Utah

Victor Santana, MD

Comprehensive Cancer Center, St. Jude Children's Research Hospital

Caitlin Sanford, MBA, CCRP

Memorial Sloan Kettering Cancer Center

Jaime Wurth, CCRP

Masonic Cancer Center, University of Minnesota

1:20 PM Break

1:35 PM Completing the NCI Cancer Center Support Grant and Meeting New Expectations

Panelists will explore recent changes to the National Cancer Institute (NCI) Cancer Center Support Grant, with a focus on the P30 Funding Opportunity Announcement, and how cancer centers can successfully navigate the application process and conduct virtual site visits, if needed. They will also discuss modifications to and future application of the clinical trials reporting program.

Moderator: Alex Zafirovski, MBA

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

Henry Ciolino, PhD

National Cancer Institute

Carrie Lee, MD, MPH

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

Gisele Sarosy, MD

National Cancer Institute

2:40 PM Regulatory Work Simplified: Providing Higher Quality Service to Sponsors

Vendor Presentation: Complion

In a time of remote work, as inefficiencies are further highlighted, many are considering technology investments to make work easier and more effective. But how do you go about choosing the right vendor to partner with for regulatory work management on all of your studies? During this presentation, Complion will review core understandings that need to be shared across the entire internal decision-making team, including cost, the need to prioritize regulatory-related investments, and the aspects of technology that are best suited to the needs of your clinical trials office.

Jaclyn Clark

Complion

3:10 PM Closing Remarks

Theresa L. Werner, MD

Huntsman Cancer Institute, University of Utah

AACI CRI Meeting 2020 Abstracts

FIRST PLACE: Standardized and Personalized Training Results in Increased Job Satisfaction and a Reduction in Turnover

K. Jenkins, J. Workman, L. Mooney, M. Kilbane

Cleveland Clinic Cancer Center

SECOND PLACE: The Challenges and Successes of Enrolling Participants on the Tomosynthesis Mammographic Imaging Screening Trial (TMIST or study EA1151) in Hawaii's Minority/Underserved NCI Community Oncology Research Program (M/U NCORP)

S. Cheng¹, S. Wakuk¹, S. Lieu¹, N. Ramos¹, K. Bryant-Greenwood¹, K. Cassel¹, J. Berenberg¹, M. Ka'aihue², R. Lee², E. Capps²

¹University of Hawai'i Cancer Center, University of Hawai'i at Mānoa; ²Queen's Medical Center

THIRD PLACE: Enhancing Productivity: Utilizing the ONBASE Application and Pharmacist Created Order Sets to Streamline the Trial Launch Process

B. Secor, I. Reveles, D. Yzquierdo, A. Rodriguez, M. Nashawati, M. Tomasini, P. Manea

Mays Cancer Center, UT Health San Antonio

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

Clinical Research Operations

- 1. Metropolitan Management of Mitten-wide Clinical Trials: Coordination From Our Own Backyard**
J. Ventimiglia, E. Doppel, B. Olsen
Barbara Ann Karmanos Cancer Institute, Wayne State University
- 2. The Dog Ate My Pill Diary and Other Stories From the Frontlines of Drug Accountability**
C. Galasso, B. Dickow, C. Houde, J. Ventimiglia, M. Ventimiglia, C. Zack, C. Zuccaro
Barbara Ann Karmanos Cancer Institute, Wayne State University
- 3. * Centralized Research Patient Scheduling & Authorizations**
R. Chiechi, P. Herena, M. Kenney, B. Williams, M. Licata
City of Hope Comprehensive Cancer Center
- 4. Research Operations Innovation Program**
R. Chiechi, S. Rosen, A. Lee, M. Licata, M. Kenney, A. Hammond, M. Bush, J. Light
City of Hope Comprehensive Cancer Center
- 5. Operationalizing Protocols Through Treatment Plan Guidelines**
M. Licata, C. Krygsman, P. Mack, A. Chung, A. Yi, A. Lee, R. Chiechi, P. Herena, B. Williams
City of Hope Comprehensive Cancer Center
- 6. Moving Cellular Therapy Clinical Trials in the Outpatient Setting: Aligning With Institutional Standards and FACT**
P. Herena, M. Licata, B. Williams, C. Krygsman, R. Chiechi, A. Lee, M. Shields, A. Chung
City of Hope Comprehensive Cancer Center

- 7. Improving Staff Engagement and Retention Through a Staff Engagement Committee and Subsequent Collaboration Between Staff and Management**
A. Toth, K. Grimaldi, C. Light, N. Ross, S. Zamora, D. Cohen, E. Love
Laura and Isaac Perlmutter Cancer Center at NYU Langone
- 8. Optimizing Clinical Trial Conduct for CAR T Therapies Improves Trial Efficiency**
J. Bruggeman, G. Bouska, K. Croghan, C. Grimont, M. Burt, C. DuBois, Y. Lin
Mayo Clinic Cancer Center
- 9. One Small Step: Eliminating Investigator Sign-offs on Individual Epic Lab Reports**
R. Selle, J. Thomas, B. Oleson
Medical College of Wisconsin Cancer Center
- 10. Clinical Research Strategic Partnerships (CRSP) Program Initiatives and Future Goals**
S. Salvati, S. Yoon
Memorial Sloan Kettering Cancer Center
- 11. Optimizing Our Protocol Management System Data and Aiding Research Portfolio Decisions Through Use of Custom Dashboards**
J. Migliacci, B. Seko, A. Bijwe, S. Hanley, K. Kaufman, J. Lengfellner, R. Cambria, A. Rodavitch
Memorial Sloan Kettering Cancer Center
- 12. Registering 100% of Clinical Trial Participants: How Memorial Sloan Kettering Ensures Registration Accountability**
R. Panchal, M. Buckley, B. Search, K.-H. Lin, D. Caron-Fabio, J. Yan, J. Lengfellner
Memorial Sloan Kettering Cancer Center
- 13. Staffing Model Reported Effort and Study Budgets: Are We In Sync?**
E. Siglinsky, S. Goksu, H. Phan, K. Crane, M. Beg, E. Williams
Simmons Comprehensive Cancer Center, UT Southwestern Medical Center
- 14. Utilizing the Clinical Trial Management System (CTMS) to Batch Load Accrual Data to the Clinical Trials Reporting Program (CTRP) System**
M. Aguilar¹, S. Antony¹, E. Williams¹, S. Nonemaker-Cox²
¹Simmons Comprehensive Cancer Center, UT Southwestern Medical Center; ²Essex Management
- 15. Creating a Culture of Continuous Improvement in a Cancer Clinical Trials Office**
E. Anderson, Y. Pang, L. Craveiro, B. Hann, A. Nika
Stanford Cancer Institute
- 16. New Study Feasibility: Harnessing the Power of REDCap**
M. Ashland, L. Craveiro
Stanford Cancer Institute
- 17. Conquering Resourcing**
B. Broome, D. Pal Mudarantakam
The University of Kansas Cancer Center

2020 Abstracts

18. Connecting the Chain – Part Two

D. Pal Mudaranthakam¹, J. Thompson¹, D. Streeter¹, R. Jensen¹, M. Mayo¹, A. Chahal², S. Yadav², J. McIlwain²

¹The University of Kansas Cancer Center; ²nCoup Inc.

19. Adverse Event Reporting System

A. Annis, M. McAdoo, A. Hanlyn, Z. Feng, A. Smith, K. Simpson

UAMS Winthrop P. Rockefeller Cancer Institute

20. Arkansas-Patient Study Calendar

K. Simpson, A. Annis, C. Golden, Z. Feng, A. Smith, K. Zorn

UAMS Winthrop P. Rockefeller Cancer Institute

21. Using Video Remote Interpretation to Overcome Language Barriers With Non-English Speakers in Clinical Trials

C. Garcia, J. Bourgeois, D. Harvey, C. Lewis

Winship Cancer Institute of Emory University

22. Winship Clinical Trials Office CAPA Review Process – CAPA Review Team

P. Bourbo, C. Sharp, K. Nguyen, T. Kurilo, M. Hananel

Winship Cancer Institute of Emory University

23. Piloting a "Just-in-Time" Model to Improve Efficiency and Accuracy in Phase I Clinical Trials Pharmacy Order Creation Process

E. Judson-Barton, M. Williams, C. Belmore

Winship Cancer Institute of Emory University

Finance/CCSG/PRMS

24. Capturing Metrics for the First Stage of Protocol Review at a Consortium Cancer Center

K. Hoy¹, A. Firstencel¹, H.J. Pounardjian¹, J. Chan¹, K. Jenkins², L. Mooney², M. Kilbane²

¹Case Comprehensive Cancer Center; ²Cleveland Clinic Cancer Center

25. Building the NCI Network Program

L. Gaffney, J. Mohr, M. Warren, C. Aghajanian, P. Sabbatini, E. Cottingham, L. Deen, B. Zakrzewski, J. Klinger, S. Dominguez, C. Houston

Memorial Sloan Kettering Cancer Center

26. Memorial Sloan Kettering's Protocol Review Core: A Specialized Approach to Protocol Review Committee Management

S. Hanley, J. Migliacci, C. Ryan, X. Lekperic, K. Napolitano, A. Rodavitch

Memorial Sloan Kettering Cancer Center

27. * Time is Money: The Impact of Clinical Research Finance Centralization

C. Sanford, B. Zakrzewski

Memorial Sloan Kettering Cancer Center

28. Utilizing OnCore Capabilities to Automate Annual Continuation Review Submissions to PRMC

S. Phillips

Siteman Cancer Center

29. Building the Post-award Management Infrastructure and Process Support to Reduce Turnaround Time to Collect Study Invoice(s) for Sponsor Clinical Trials

P. Chang

Stanford Cancer Institute

30. Clinical Research: Following the Money

C. Golden, A. Annis, L. Hutchins, D. Drum, R. Geary, A. Smith, Z. Feng, N. Pruss

UAMS Winthrop P. Rockefeller Cancer Institute

31. Revising an Institutional PRMC Charter to Achieve NCI Standards: Impacts, Efficiencies, and Potential for Further Improvement

C. Vollmer, N. Kurtzweil, C. Allen, E. Kantemneni, T. Herzog

UC Cancer Center

32. Streamlining Feasibility Assessment Within the Scientific Review Process

A. Anderson, A. Ivey, T. Guinn, T. George

University of Florida Health Cancer Center

33. An Approach to Revitalizing PRMS Scientific Progress Reviews

S. Brogan, D. Martinez

Yale Cancer Center, Yale School of Medicine

Investigator-Initiated Trials

34. The Sample Collection and Tracking Process for Multisite Investigator-Initiated Trials

A. Bauchle, L. Sego

Indiana University Melvin and Bren Simon Cancer Center

35. Stimulating Investigator-Initiated Trial Development: A Comprehensive Approach to Provide Guidance, Mentorship, and Logistical Support for Principal Investigators

A. Anshu, B. Oleson, B. Brito, M. Larson, A. Szabo, K. Marquardt, E. Gore, H. Rui, J. Thomas, B. Shaw, S. Wong

Medical College of Wisconsin Cancer Center

36. A Risk-Based Approach to Monitoring and Auditing Multicenter Investigator-Initiated Trials

K. Muenkel, S. Hughes, J. Walkley, M. Warren, A. Granobles, F. Puma, S. Puleio, K. Yataghene, C. Houston

Memorial Sloan Kettering Cancer Center

37. Increasing Interventional Treatment IITs in the Study Start-up Pipeline With an IIT Committee Approach

N. Kurtzweil, S. Palackdharry, M. Racic, T. Wise-Draper

UC Cancer Center

38. * Investigator-Initiated Trials in the Wild, Wild West: Implementation of the Oncology Clinical Research Support Team at the University of Colorado Cancer Center

S. Grolnic, T. Cull

University of Colorado Cancer Center

2020 Abstracts

Regulatory

- 39. * Redesigning the Delegation of Authority Log for the Modern Cancer Center**
J. Wurth, T. Presley, J. Feola, A. Vogt, D. Bullock, D. Berkow
Masonic Cancer Center, University of Minnesota
- 40. MSKCC INDs Multicenter IITs: A Centralized Model in Regulatory Oversight**
H. Pham, W. Blouin, S. Yoon, J. Walkley, R. Ellis, M. Warren
Memorial Sloan Kettering Cancer Center
- 41. The Regulatory and Product Development Road to the Future of Cancer Care**
A. Yadav, R. Ellis, Z. Shabani, D.A. Ho, L. Shrestha, M. Varghese, H. Pham
Memorial Sloan Kettering Cancer Center
- 42. Electronic Regulatory Binders – A Homegrown System**
M. Kovak, D. Wade, B. Scanlon, B. Lehman, J. Holley, P. Newman, L. Hutchins, A. Annis
UAMS Winthrop P. Rockefeller Cancer Institute
- 43. Assessing an ASCO Decision Aid for Improving the Accuracy and Attribution of Serious Adverse Event Reporting From Investigators to Sponsors**
L. Byatt¹, K. Mileham², S. Bruinooge³, C. Davis³, E. Garrett-Mayer³, P. Hurley³, L. Levit³, C. Schenkel³, M. Chuk⁴, A. Buchmeier⁵, R. Perez⁶, J. Vose⁷
¹University of New Mexico Comprehensive Cancer Center; ²Levine Cancer Center, Atrium Health; ³American Society of Clinical Oncology; ⁴U.S. Food and Drug Administration; ⁵Sarah Cannon Research Institute; ⁶Bristol Myers Squibb; ⁷University of Nebraska Medical Center

Training & Quality Assurance

- 44. Use of REDCap Database to Identify Trends in Non-compliance**
A. Kale, N. Cassim
City of Hope Comprehensive Cancer Center
- 45. The Case for Physician-Led Education Sessions for Research Coordinators**
L. Waitkus
Cleveland Clinic Cancer Center
- 46. Standardized and Personalized Training Results in Increased Job Satisfaction and a Reduction in Turnover**
K. Jenkins, J. Workman, L. Mooney, M. Kilbane
Cleveland Clinic Cancer Center
- 47. "Who Cares? It's Just a Minimal Risk Study": The Case for Research Compliance Oversight of Cancer Population Sciences (CPS) Research**
E. Beck, K. Thorne
Huntsman Cancer Institute, University of Utah

- 48. * Development of a Competence-Based Quality Assurance Program**
R. Kingsford, J. Espinosa, S. Sharpy, J. Moehle, L. Lujan, T. Werner
Huntsman Cancer Institute, University of Utah
- 49. Advising and Trial Guidance for Investigators**
L. Sego, A. Bauchle, S. Edwards
Indiana University Melvin and Bren Simon Cancer Center
- 50. New Employee Orientation – Joining the 21st Century**
F. Kerr, M. Cheviron, S. Edwards, S. Asche
Indiana University Melvin and Bren Simon Cancer Center
- 51. Training the Masses – Electronic Protocol Training**
J. Norfleet, F. Kerr, S. Asche, J. Nichols
Indiana University Melvin and Bren Simon Cancer Center
- 52. Approaching Goals With a Plan: Application of MSK Resources for Internal Audit Process Improvement**
C. Duarte
Memorial Sloan Kettering Cancer Center
- 53. Improving Clinical Research Quality and Efficiency Through the Implementation of a Risk-Based Audit Approach**
S. Puleio
Memorial Sloan Kettering Cancer Center
- 54. Expanding the Scope of an Internal Quality Assurance Program to Initiate Change on a Mezzo- and Macro-level**
E. Harms, N. Borror, K. Williams
Siteman Cancer Center
- 55. A Process for the People: Updating Oral Medication Compliance Policy, Guidelines, and Tools**
N. Borror, E. Harms, K. Williams, L. Menne
Siteman Cancer Center
- 56. Protocol-Specific Training in a Commercial IRB World: Adjusting the Process to Ensure Training Keeps Up**
L. Menne, E. Harms, N. Borror
Siteman Cancer Center
- 57. UF Health Cancer Center (UFHCC) Research Fantasy League: A Novel Approach to Employee Engagement**
T. Guinn, A. Anderson, A. Ivey, R. Houlihan
University of Florida Health Cancer Center
- 58. Minimizing Clinical Trial Deviations Through Lean Six Sigma and a CRO Compliance Committee**
A. Barkman, T. Cummings, J. Kessler
University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center
- 59. Research Staff Orientation and Training**
M. Horak, D. Cleary, B. Pappu
UPMC Hillman Cancer Center

2020 Abstracts

60. Development of an Integrated Orientation Program Using the Joint Task Force Core Competencies for Research Professionals

E. Gainey, G. Beals

Vanderbilt-Ingram Cancer Center

61. Let It Go! One Strategy to Maximize Limited QA Resources

A. Gateman, E. Smas

Yale Cancer Center, Yale School of Medicine

Trial Recruitment & Community Outreach and Engagement

62. Crack the Walnut! How Community Outreach Research Coordinators Can Empower African American Men to Come Out of Their Shell to Make an Informed Decision About Prostate Cancer Screening, a Cancer Prevention Project

C. Chapman, K. Hunt, E. Meisler, D. Allen, S. Abraksia, A. Seals, N. Anderson, K. Sanders

Cleveland Clinic Cancer Center

63. * Completing the Circle: Lay Summary of Protocol Results for Study Participants

V. Santana, D. Wallace, D. McGarry, E. Walker, L. Tanner, J. English

Comprehensive Cancer Center, St. Jude Children's Research Hospital

64. A Quick Guide to Affiliate and Satellite Site Activation and Oversight Process

G. Nachaegari

Huntsman Cancer Institute, University of Utah

65. The Challenges and Successes of Enrolling Participants on the Tomosynthesis Mammographic Imaging Screening Trial (TMIST or study EA1151) in Hawaii's Minority/Underserved NCI Community Oncology Research Program (M/U NCORP)

S. Cheng¹, S. Wakuk¹, S. Lieu¹, N. Ramos¹, K. Bryant-Greenwood¹, K. Cassel¹, J. Berenberg¹, M. Ka'aihue², R. Lee², E. Capps²

¹University of Hawai'i Cancer Center, University of Hawai'i at Manoa; ²Queen's Medical Center

66. The Reinvigoration of Alliance Membership and Accrual: From Almost Losing Membership to a High-Performing Site in 2 Years

M. Russell, D. Kitterman, O. Danciu, J. Quigley

University of Illinois Cancer Center

67. Minority Accrual to Therapeutic Clinical Trials

M. Russell, D. Kitterman, O. Danciu

University of Illinois Cancer Center

Trial Start-up and Activation

68. * The Road to 90

M. Kelley, K. Donahue, M. Gorno, S. Bigelow, R. Jarrard, P. Dykema, R. George, V. Davis, V. Gorden

Barbara Ann Karmanos Cancer Institute, Wayne State University

69. Sponsor and Collaborator Content Management System

G. Balagot, N. Cassim

City of Hope Comprehensive Cancer Center

70. Redefining Clinical Trial Start-up Through Continuous Improvement

A. McCorkle, L. Mooney, M. Kilbane

Cleveland Clinic Cancer Center

71. Improving Study Start-up Timelines: A Comprehensive, Multidisciplinary, Process-Improvement Initiative

S. Skendzel, E. Orcholski, D. Krishnadas, R. Nicklow, M. Lindemann, M. Morris, J. Bruan

Masonic Cancer Center, University of Minnesota

72. Enhancing Productivity: Utilizing the ONBASE Application and Pharmacist Created Order Sets to Streamline the Trial Launch Process

B. Secor, I. Reveles, D. Yzquierdo, A. Rodriguez, M. Nashawati, M. Tomasini, P. Manea

Mays Cancer Center, UT Health San Antonio

73. Clinical Trials Time to Activation: The Process, Structure, and People

Y. Suri, M. El Shayeb

O'Neal Comprehensive Cancer Center at the University of Alabama at Birmingham

74. C3OD User Interface – A Simple and Intuitive Solution to Feasibility Analysis for Clinical Trials

D. Pal Mudarantakam, J. Thompson, D. Streeter

The University of Kansas Cancer Center

75. Time to Activation: Are We Comparing Apples to Apples?

A. Skafel, K. Shumate

UCSF Helen Diller Family Comprehensive Cancer Center

76. Reducing Burdens of Site Feasibility Assessments for Conducting Clinical Trials

L. Byatt¹, P. Hurley², C. Davis², J. Hofacker³, E.S. Kim⁴, D.M. Waterhouse⁵, G.S. Nowakowski⁶, D. Kurbegov⁷

¹University of New Mexico Comprehensive Cancer Center; ²American Society of Clinical Oncology; ³Association of American Cancer Institutes; ⁴Levine Cancer Institute, Atrium Health; ⁵Oncology Hematology Care, Inc.; ⁶Mayo Clinic Cancer Center; ⁷Sarah Cannon Research Institute

77. Automatic Study Cost-Outs: A Tool Designed to Objectively Assess Trial Operations Costs for More Standardized and Efficient Budget Negotiations While Improving Overall Study Time to Activation

J. Plassmeyer, M. Yarkowski, G. Hickman, B. Crocker, K. Richter, K. Yee

UPMC Hillman Cancer Center

AACI CRI Supporters

AACI gratefully acknowledges support from the following:

Gold Level



Silver Level



Bronze Level



AACI Corporate Roundtable Members

AACI is grateful for the support of the 2020 Corporate Roundtable members:



AACI CRI Exhibitors

AACI gratefully acknowledges support from the following:



AACI CRI Exhibitors

Advarra, home of Forte Technology Solutions

Advarra empowers institutions to manage studies more easily, improve compliance, and streamline operations as the premier provider of global research compliance services, offering IRB, IBC, consulting, and research technology solutions. Forte software and services, now part of Advarra, provide clinical trial management, clinical data management, and research administration for more than 70 percent of NCI-Designated Cancer Centers.

With a strong belief in community, collaboration, and standards-based development, the company also facilitates the Onsemble Community, a customer-exclusive group for peer networking, best practices, and support. Additionally, Advarra helps make research altogether better with proven capabilities in research administration, HRPP, biosafety, billing compliance, regulatory, GxP auditing, clinical quality assurance, and interim professional staffing. For more information, visit advarra.com.

ASCO

The American Society of Clinical Oncology and the Association for Clinical Oncology are committed to making a world of difference in cancer care. The Society and the Association represent nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, the Society works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. The Association works to ensure that all individuals with cancer have access to high-quality, affordable care; that the cancer care delivery system supports oncology providers in their delivery of optimal cancer care; and that our nation supports federal funding for cancer research as well as efforts centered on cancer prevention, drug development, and clinical trials. Learn more about the Society at ASCO.org, explore patient education resources at Cancer.net, and follow us on Facebook, Twitter, LinkedIn, Instagram, and YouTube. Learn more about the Association at ascoassociation.org and follow us on Twitter.

Complion

Complion is the eRegulatory pioneer, created by a researcher for researchers. The regulatory document and workflow management platform stores, organizes, and routes clinic trial documentation to enable seamless, paperless processes. Surpassing simple documentation digitization, Complion leverages advanced technology to intelligently file documents and provide controlled access to staff and monitors.

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Essex Management

Essex Management is a biomedical informatics and health information technology-focused consultancy founded in 2009, and headquartered in Rockville, MD. 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 #1 eISF platform in clinical research powering the document workflows of more than 7,200 study sites across 26 countries. In addition to streamlining internal workflows across eReg, eSource, eLogs, SOPs, contracting, and credentialing, research sites use Florence to remotely connect with study sponsors and CROs via our industry-first remote monitoring and access platform.

As the eISF becomes a requirement in research, we are dedicated to your successful implementation, training, and ongoing success. Our team works with you to build and execute a change management strategy to quickly ramp-up adoption and usage across your organization.

We look forward to Advancing Research Together with you.

Huron

Huron's cancer center team is composed of leaders with 20-plus years of front-line experience in academic-based cancer centers. They rely on their 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, improving health, spurring innovation and advancing knowledge.

Veeva Systems

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 850 customers, ranging from the world's largest pharmaceutical companies to emerging investigative sites. For more information, visit veeva.com.



Restore Your Research

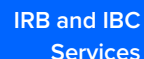
Build a solid foundation for your institution to thrive in the new normal. Improve visibility into your research operations, streamline study activation, enhance compliance, build remote workflows, and enable strategic decision-making across your enterprise.



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



Enhance regulatory compliance, boost staff productivity, and gain efficiency with an eRegulatory system ideal for remote workflows and monitoring.



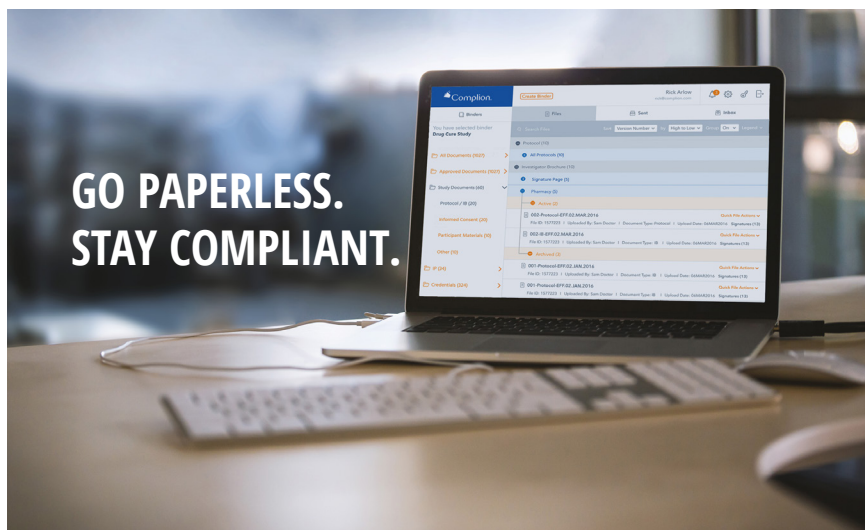
Utilize the IRB trusted by more than 80% of AACI members, and the single IRB for the NCI Cancer Moonshot and ACCRU.

Building a Foundation to Thrive in the New Clinical Research Landscape

TUESDAY, JULY 7 • 2:40–3:10PM EDT

Join us after the AACI-CRI keynote to gain valuable insight into the changing research environment. We will provide an overview of the current state of clinical research, where the industry is headed, and how you can set your institution up for success.

advarra.com • forteresearch.com



**GO PAPERLESS.
STAY COMPLIANT.**

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

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

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

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

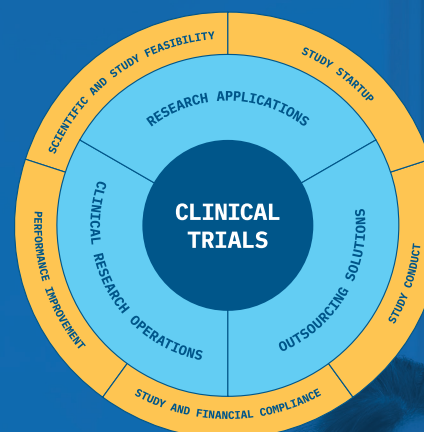
- ✓ Quickly find the right document with better organized files, standard templates, and powerful keyword search.
- ✓ Reduce time managing PI delegation records, Safety Reports, CVs, Licenses and training with Part 11 compliant signatures and site-centric workflows.
- ✓ Eliminate printing and redundancy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

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



Huron understands cancer centers.

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



Enhance clinical research operations.

Streamline research administration.

Provide strategic advice.

Prepare for National Cancer Institute designation.

huronconsultinggroup.com/resources/higher-education/strategic-solutions-cancer-centers



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