SCHEDULE-AT-A-GLANCE

Pre-Conference Thursday, September 25, 2025

8:00 AM - 5:30 PM **Clinical Research Professional Certification Preparation and GCP Course**

1:00-5:15 PM **Pre-Conference Workshops**

Budgeting, Contract Negotiation & Finance
Speakers: Dawn Pittinger, DBA, MBA-HA, CHRC, CHC, CCP, CHA & Candida Barlow, PhD, MSN, CRN-BC, RN

ClinicalTrials.gov - What Administrators Need to Know
Speaker: Cristina Ferrazzano Yaussy, MPH, CCRP

Device Research Regulatory Basics
Speakers: Kathi Durdon, MA, CCRP & Angie Rock, MBA, CCRP

Investigator-Initiated Sponsored Research (IISR)
Speakers: Harvey Arbit, PharmD, MBA, CCRP, RAC & Wrenda Teeple, PharmD, BCPS

Statistics in Clinical Research: Understanding the Basic Concepts
Speaker: Mark Krailo, PhD

Optimal Study Start-Up Through Protocol Assessment
Speaker: Janelle Allen, BS, MS, CCRP

Preparing for the FDA Clinical Investigator Site Inspection
Speaker: Tammy Neseth, MA, CCRP, CIP

Quality Management
Speakers: Alyssa Gateman, MPH, CCRP & Abby Statler, PhD, MPH, MA, CCRP

Foundations of Clinical Research Project Management
Speakers: Jessica Thompson, MS, MBA, PMP & Amy Selegue, BA, BSN, MLS, CCRP

6:00-8:00 PM **Business Meeting and Welcome Reception**

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FOR CLINICAL RESEARCH EXCELLENCE

SCHEDULE-AT-A-GLANCE

Friday, September 26, 2025

7:30-8:30 AM **Breakfast**

8:30-9:15 AM **Welcome: Opening Remarks & Award Presentations**

9:15-10:00 AM **Opening Plenary:** Research Advocacy Under a New Administration: Insights and Actions Panel
Panelists: Barbara Bierer, MD; Gabriel T. Bosslet, MD; and Savannah G. Sims, PhD
Moderator: Jessica L. Rowe, MA, MS, CIP, CCRP

10:00-10:30 AM **Morning Break with Posters and Exhibits**

10:30-11:15 AM **Opening Plenary:** Fireside Chat with Yvonne C. Collins, MD: Partnership & Engagement with the NIH All of Us Research Program
Moderator: Catherine Hudson, DrPH, CCRC, CCRP

11:15 AM-12:00 PM **Opening Plenary:** Combating Burnout: Strategies for Sustaining Well-Being Among Clinical Research Professionals
Speaker: Karen Moody, MD, MS

	Decentralized Clinical Trials	**Enrollment/ Retention & Informed Consent**	**IDEA in Clinical Research Behavior**	**Investigator Initiated Research**	**Training**	**IRB**	**Device Research**	**Monitoring Effectiveness**
1:15-2:00 PM	Deconstructing Silos- Clinical Research Speaker: Candida Barlow, PhD, MSN, CRN-BC, RN	Should Your Patient Recruiting Engine Be Gas, Electric, or Hybrid? Speaker: Mark Metzner	The Times and the FDA are Changing, are You? Speaker: Sara Saunders, MHA, CCRP & Catherine Gregor, MBA, CCRC, CCRP	FTC and FDA Oversee Claims About Benefits and Safety of Health-related Products. Speaker: Harvey Arbit, PharmD, MBA, CCRP, RAC	Research Ambassador program at the Mass Alzheimer's Disease Research Center Speaker: Jin hui Joo, MD, MA	Soldiers serving as Subjects: IRB chair reports from the front lines Speaker: Lester Lacorte, MD, CCRP	The GDPR and International Data Privacy Regulations: Overview and Impact on Clinical Trials Speakers: Ethan Denny, JD and Scott Shurtleff, JD	FDA and EMA Inspection Findings: Lessons Learned Speaker: Janet Holwell, BA, FACRP, CCRC, CCRA, TIACR
2:05-2:50 PM	Decentralized Clinical Trials (DCTs): Are They Here to Stay? A Compliance Perspective Speaker: Asha Shukla (Sharma), PhD, MS, MSc, PGDCRM, CCRP	Vulnerability in Clinical Trials: Impact of Age and Circumstance Speaker: Mary Cataletto, MD, MMM	Equitable Participation in Research: Removing Barriers for Minority Populations Speaker: Muhammad Waseem, MD, MS, CCRP	Investigator-initiated Research: Best Practices from the Sponsor Perspective Speaker: Daniel Redline, BA, CCRP	ABCs of GCP 101 - A Session for the New Study Coordinator Speaker: Tammy Neseth, MA, CCRP, CIP	Building Bridges: Enhancing Investigator Understanding of IRB Review Processes Speaker: Diane Makled, Pharm, MSc, CIP, ACRP-CP	The GDPR and International Data Privacy Regulations: Overview and Impact on Clinical Trials Speakers: Ethan Denny, JD & Scott Shurtleff, JD	Clinical Risk-Based Monitoring Plan for Multi-centered Clinical Trials: Workflows for Development Speaker: Crystal Santillanes, MS

SCHEDULE-AT-A-GLANCE

Friday, September 26, 2025, cont'd

2:50-3:25 PM **Afternoon Break with Posters and Exhibits**

3:25-4:10 PM	**Decentralized Clinical Trials** Clinical Trials Beyond Walls: a Centralized Consult Service for Implementing Decentralized Clinical Trials Speaker: Emily Breutzman, RN, BSN & Danielle Shrader, CCRP	**Project Management** How to Use REDCap to Improve Study Workflow Speaker: Katie Hofmann, BS, REDCap Admin	**IDEA in Clinical Research Behavior** Exploring the Demand for Clinical Trials in Rural Communities Speaker: Autumn Thompson, BS, CCMA (AAMA), CPT	**Investigator Initiated Research** Using Research Electronic Data Capture (REDCap) to Enhance Research Pharmacy Operation Speaker: David Chan, PharmD, PhD, BCOP, CCRP	**Training** Anchoring Talent: Tips for Young Professionals and Employers in Clinical Research Speakers: Lady Ramirez Molina, BS, CCRP; Emily Schultz, CCRP; Lauren Anderson, MHA, PMP, CCRP; Caroline Caraci, PMP, CCRP	**International Trials** Implementation of R3 Updates Speakers: Jeannie Farnsworth, MS, BS, CCRP; Susan Hmwe, PhD, MBBS, MS, CCRP; and Rachel Kingsford, MS, CCRP	**Device Research** The MDCG Guidance Documents and EU MDR: What Do I Need to Know for Device Trials int he EU Speaker: Dan Redline, BA, CCRP	**Monitoring Effectiveness** Participant Safety in Adverse Event Reporting Speaker: Jennifer Mohnacky, MS, RDN, CCRP
4:15-5:00 PM	**Decentralized Clinical Trials** Empowering Rural Clinicians: Enhancing Clinical Trial Participation through Research Readiness Training Speaker: Mary Christie, MSBA, CCRP	**Enrollment/ Retention & Informed Consent** Using Biospecimen Collections to Help Advance a Research Program in Rural Kentucky Speaker: Mike Brunet, PhD, ATC, CPT, STS	**Pediatric Research** Ethical Considerations in Clinical Research Speaker: Steven Klintworth, BSN, MSHS, RN, CCRP	**Investigator Initiated Research** Data Management for Investigator-Initiated Trials Speaker: Amy Staroscіak, PhD	**Training** Principal Investigator Boot Camp:'Basic Training' for the New & Experienced Researcher Speaker: Laura Adkins, MAP, CCRP, CCRA	**International Trials** Principal Investigator Boot Camp:'Basic Training' for the New & Experienced Researcher Speaker: Laura Adkins, MAP, CCRP, CCRA	**Device Research** Advancing Device Innovation: Early Feasibility Studies with MDIC, Industry, and Site Collaboration Speaker: Eileen Mihas, RN, MSN-HSL, NC-BC	**Monitoring Effectiveness** Hot Topics in Monitoring: AI, DCTs, and Getting Credit for Your Good Work Speaker Sarah Moeller, MS

SCHEDULE-AT-A-GLANCE

Saturday, September 27, 2025

7:30-8:30 AM **Breakfast**

8:30-9:15 AM	**Poster Sessions** Poster Presentations: Clinical Trials Moderators: John Petrich, MS, RPh & Joanne Goldberg, MSc, pht, CCRP	**Enrollment/Retention & Informed Consent** It Takes More Than Words in The Informed Consent Process: Enhancing Compliance, Communication, and Comprehension Speaker: Nancy Wintering, MSW, LCSW, CCRP	**Project Management** Project Management Tools for Investigator-Initiated Trials Speaker: Amanda Galster, MPH, CCRP		**International Trials and ICH** Clinical Research Terminology Speaker: Tatjana Markovic, MA, AS	**Training** Shall we play a game? Advancing Clinical Research with Game Theory Speaker: Bashar Shihabuddin, MD, MS	**Device Research** Expanded Access Devices: Regulatory Pathways and Physician Responsibilities Speaker: Amrita Ghosh, B.Pharm, RAC	**Site Management** Navigating CRC Turnover Using a Transition Plan Speaker: Poonam Prasad, MHI, BA, CCRP
9:20-10:05 AM	**Poster Sessions** Poster Presentations: Clinical Research Management Moderators: John Petrich, MS, RPh & Joanne Goldberg, MSc, pht, CCRP	**Enrollment/Retention & Informed Consent** Documentation of Informed Consent: Strategies to Prove Compliance Speaker: Rachel Kingsford, MS, CCRP	**Project Management** Service Provider Selection and Management for Sites, CROs and Sponsors Speaker: Fraser Gibson, MBA, PMP	**Regulatory** Revolutionizing Regulatory Affairs for Clinical Research with AI Speaker: Titlayo Olubajo, MD, MSM-HCA, CCRP	**Canadian Regs/Inspections** FACT Standards and the Canadian Regulatory Landscape – Views from an Academic Centre Speaker: Ekaterina Hult, MSc, CCRP	**Training** Quality and Compliance in Human Research: A Continuous Learning Process and Requirement for Trust in Science Speaker: Casey Jackson, MS, CCRP	**Device Research** CMS Criteria for Approving IDE Studies - Best Practices Speaker:Wendy Schroeder, BSN, CCRC-PM, CRCP	**Site Management** Demystifying Risk-based Monitoring for Sites Speaker: Leslie Donnelly, RN, BSN

10:05-10:50 AM **Morning Break with Posters and Exhibits**

SCHEDULE-AT-A-GLANCE

Saturday, September 27, 2025, cont'd

	Quality Management	Advanced Management	Project Management	Regulatory	Canadian Regs/Inspections	Training	Device Research	Site Management
10:50-11:35 AM	Leveraging Audits to Prevent Future Noncompliance Speaker: Dawn Pittinger, DBA, MBA-HA, CHRC, CHC, CCP, CHA	Unraveling Investigator Change: Understanding the Nuances Speakers: Wendy Portier, MSN, RN, CHRC, CHC, CPC & Cynthia Dunn, RN, MSN, CCRA, CCRP, CHRC, CPC	Wrangling Chaos: Real-World Project Management for Research Teams Speaker:Casey Snoddy, BS, CCRP	IRB when and how to request waivers related to consent Speaker:Julie Haltiwanger, MPA, CIP, CHRC, CCRP	Readiness for ICH E6(R3) Implementation in Canada Speaker:Janette Panhuis, BScN, MBA	Implementation of a One Signature Initiative at a Large Academic Medical Center Speaker:Elizabeth Robison, BS, CCRP	In Vitro Diagnostics - Clinical Performance Studies Speaker: Narvelle Delabruere, MSc	Bridging the Research Barriers Between Sites, CROs, and Industry Speaker: Jeannie Farnsworth, MS, BS, CCRP
11:40 AM-12:25 PM	Key Success Factors for Adopting a Quality by Design Methodology Speaker: Melisa Williamson	Localising Global Research - Why is it so hard? Speaker: Sara Saunders, MHA, CCRP	Be the Voice You Want Your Leader to Possess: A Deep Dive into Effective Leadership in Clinical Research Speaker: Jessica Fritter, DHSc, MACPR, ACRP-CP	Regulatory Requirements for Registering & Reporting 42 CFR Part 11 and NIH-funded Clinical Trials in ClinicalTrials.gov Speaker: Susan Hmwe, PhD, MBBS, MS, CCRP	Clinical Trial Inspection:Candian Perspective Speaker: Hocine Abid, MBA, MD	Implementing Clinical Investigator Training Speaker: Sean Hildebrandt, MS & Katrina Croghan, MS, CCRP	Defining Metrics for Monitoring Medical Device Studies - Risk-based and on-site Speaker: Ashish Indani, MBA	Research Institute Creating a Regulatory-Ready Mindset: A Quality Management Model Speaker: David Staley, MA

12:25 - 1:40 PM **Lunch, Networking, Exhibits, and Posters**

12:25 - 1:40 PM **Item Writers Lunch**

SCHEDULE-AT-A-GLANCE

Saturday, September 27, 2025, cont'd

	Advanced Management	Data Management	Quality Management	Oncology Research	Finance and Billing	Training	Ethics in Research	Site Management
1:40-2:25 PM	Exploring the Pros and Cons of Clinical Research Team Structures for a Site Speakers: Lindsay Anderson & Ashley Drokin	Adverse Events: Back to the Basics Speaker: Laura Adkins, MAP, CCRP, CCRA	Feedback, Analysis, and Action: A High-Power Mechanism for Process Improvement Speaker: Nicole Tosun, MS, CCRP	An overview of Clinical Operations at an NCI designated Comprehensive Cancer Center - Challenges, Opportunities, and Lessons Learned Speaker: Kira Pavlik, MPH, CCRP & Sara Raboin, PhD	Pre-Award Considerations and Practical Guidance for the Management of Clinical Trials Speaker: Taylor Saraceno, BSc	Overcoming Challenges in Clinical Research Management: Strategies that Work Speaker: Anatoly Gorkun, MD, PhD, Chartered MCIPD	When the Money Moves: How NIH Funding Shifts Reshape Compliance, Operations, and Research Integrity Speaker: Edye Edens, MA, CIP, CCRP	Building Healthy Sites: Leveraging Data to Make Strategic Decisions Speaker: Keith Wright, MBA, CCRP
2:30-3:15 PM	Enhancing Clinical Research Regulatory Excellence via CentralizatioIn of Regulatory Operations at a Health System-Based Research Institute Speaker: Pukar Ratti, MSChE, MSHCM, CIM, CCRP, FACMPE	Is Your EDC Fit for Purpose? Speaker: Patricia Smith	It's Just One Little Thing...Until it Isn't: FDA Inspections, Investigator Responsibilities, and Scientific Misconduct Speaker: Emily Knisely	Are Theranostics the Next Big Thing in Cancer Research? Speaker: Blake Norblad, MSCR, MSF, CCRP	Mastering Coverage Analysis: Ensuring Accurate Budgeting for Clinical Trials Speaker: Mehzabin Khan, MD, CHRC	Unlocking Leadership Potential: Navigating Self-Awareness and Empathy through The Enneagram Speaker: Carolina Cunha, BPharm, MBA, CMC (IBC)	A Continuing Evolution of Ethical Considerations in Clinical Research Speaker: Alyssa Gateman, MPH, CCRP	Site Management: Building, Leading, and Maintaining a Successful Site Speaker: Grace Wentzel, CCRP, CHRC

3:15-3:45 PM **Afternoon Break with Posters and Exhibits**

SCHEDULE-AT-A-GLANCE

Saturday, September 27, 2025, cont'd

	Advanced Management	Data Management	Quality Management	Oncology Research	Finance and Billing	Training	Ethics in Research	Site Management
3:45-4:30 PM	Site & Sponsor Audit Readiness Speaker: Jennifer Pages, CCRP	Piloting the Epic Reporting Workbench at Princess Margaret's Clinical Trials Support Unit and Lessons learned for Program Operationalization Speaker: Barbara Geogiades, BS (Honors)	Implementing a Quality Management System in an established Comprehensive Cancer Center Speaker: Katrina Croghan, MS, CCRP	Financial Neutrality in Oncology Clinical Trials Presenter: Kira Pavlik, MPH, CCRP	Building Strong Foundations: Research Billing Compliance and Scalable Team Growth Speaker: Cassie Cruz-Montes, MHA & Lu Zettel, MS	Strategic Training Integration: Enhancing Clinical Research Efficiency through Centralized Competency Development and Interdepartmental Collaboration at an Academic Medical Center Speaker: Hannah Coleman, MPH, CCRP	Ethical Considerations for Cell and Gene Therapy Clinical Trials Speaker: Daniel Eisenman, PhD, RBP, SM(NRCM), CBSP	How to Cut Through the Noise! Speaker: Huzalfa Hussain, ACRP-CP
4:35-5:20 PM	Mastering the Art of Clinical Research Timelines: From Concept to Execution Speaker: Jessica Thompson, MS, MBA, PMP & Amy Selegue, BA, BSN, MLS, CCRP	Compliance with Part 11: A Site's Perspective Speaker: Cristina Ferrazzano Yaussy, MPH, CCRP	Policy and Procedure Writing to Promote Compliance Speaker: Wendy Portier, MSN, RN, CHRC, CHC, CPC & Cynthia Dunn, RN, MSN, CCRA, CCRP, CHRC, CPC	Challenges of Study Start-up: One Comprehensive Cancer Center's Path Speaker: Erin Lynch, MS, CCRP & Polly Folsom, CCRP, CCRC, CPhT		Investing in Education: Developing an Innovative Clinical Research Coordinator New Hire Training Program Speaker: Meaghan Rodgers, MS, CCRP	Dispelling Myths About Clinical Research: A Deeper Analysis of a Complicated History Speaker: Quincy Byrdsong, EdD, MA, CIP, CCRP	All Aboard: Effective Onboarding Strategies for Clinical Research Speaker: Cynthia Holladay, MPA, CCRP & Jennifer Stuart, CCRP

8:00 -10:00 PM 80's Prom Dessert Party

SCHEDULE-AT-A-GLANCE

Sunday, September 28, 2025

7:30-8:30 AM	**Breakfast**
8:40- 9:25 AM	**Closing Plenary:** Leadership Unleashed: Thriving in the World of Clinical Research **Speaker:** Jessica L. Rowe, MA, MS, CIP, CCRP
9:25-10:10 AM	**Closing Plenary:** Strategies for Implementing Empowered and Innovative Inclusion Efforts When Planning and Conducting Your Clinical Research Studies **Speaker:** Sylvia Baedorf Kassis, MPH
10:30-11:15 AM	**Closing Plenary:** Fostering Collaborative Excellence: Building Successful Inter-organizational Relationships in Clinical Research **Speaker:** Avie Banks, MBA, MHA, CCRA
11:15-12:00 PM	**Closing Plenary:** Equity in Action: Implementing Social Accountability in Research for Community Impact **Speaker:** Catherine Hudson, DrPH, CCRC, CCRP

Subject to change. Updated on September 10, 2025.

For the most up-to-date details on site, refer to the event app.