GCP DIRECTIONS

Virtual Education & Networking Week

Simplifying Clinical Compliance Together

July 27-30, 2026 | 10 AM - 1 PM ET Each Day

GCP Directions Conference *is a virtual week dedicated to simplifying clinical compliance together. Join peers and experts to explore real-world challenges, share strategies, and collaborate on smarter, more effective compliance solutions.*

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Registration is free for all. Everyone is welcome.
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Program at a Glance

Date	Theme	Focus
Monday, July 27	**Quality Oversight**	How sponsors establish and demonstrate control across vendors, systems, data flows, and trial operations.
Tuesday, July 28	**Risk Management**	How teams identify, assess, prioritize, and act on clinical trial risk in ways that are practical, documented, and inspection-ready.
Wednesday, July 29	**Trial Master File**	How sponsors strengthen TMF quality, completeness, and oversight so the TMF accurately reflects the story of the trial.
Thursday, July 30	**Future-Ready Clinical Operations**	How technology, AI, systems, and evolving operating models can support compliance without introducing new risk.

Monday, July 27 – Quality Oversight	
10:00 AM ET	**Welcome and Conference Introduction**
10:15 AM	**WHERE OVERSIGHT BREAKS DOWN** *Recognize the Early Warning Signs of Weakening Oversight Before They Become Quality, Compliance, or Inspection Risks* • Identify common blind spots across people, processes, systems, and vendors • Recognize early indicators of weakening oversight and loss of visibility • Distinguish isolated issues from emerging systemic risk

	• Evaluate whether current oversight activities are focused on the areas that matter most • Understand how complexity contributes to hidden quality and compliance risks
10:45 AM	**MAKING OVERSIGHT VISIBLE** *Use Clinical Study Data Flow Maps to Strengthen Visibility, Governance, and Sponsor Oversight* • Visualize the flow of critical study data across systems, vendors, and stakeholders • Identify oversight gaps, handoff risks, and areas of limited visibility • Clarify roles, responsibilities, and governance across the study ecosystem • Strengthen risk-based oversight by focusing on critical data and processes • Leverage Clinical Study Data Flow Maps to support inspection readiness and informed decision-making
11:15 AM LIVE ONLY NO REPLAY	**LIVE AND UNFILTERED: SPEAKER Q&A SESSION** *Get face-to-face (virtually) with the previous speakers in an exclusive, live-only Q&A. This is your chance to ask the real questions—the ones you've been dying to ask but never see on a slide.* *No slides. No recordings. No judgment. Just candid conversation, behind-the-scenes insights, and the space to dig into what really matters.*
11:30 AM	**PANEL DISCUSSION: STAYING IN CONTROL** *How Do You Know Your Oversight Model is Working?* Hear directly from industry leaders as they share first-hand experiences, lessons learned, and practical strategies for addressing today's most pressing clinical trial challenges. • Determine whether you have true visibility—or just a dashboard full of metrics • The warning signs that say oversight is starting to break down • What to do when CROs, vendors, and sponsors see risk differently • How to demonstrate sponsor control without creating unnecessary oversight burden • Lessons learned from issues, audits, inspections, and near misses they didn't see coming
12:15 PM LIVE ONLY NO REPLAY	**INTERACTIVE ACTIVITY: OVERSIGHT CHALLENGE LAB** *Work Through Realistic Scenarios that Test Oversight, Visibility, and Decision-Making* Participants choose a facilitated discussion group focused on one of the following scenarios: **SCENARIO #1** **Your CRO Says Everything Is Fine. The Data Says Otherwise** *Your study is meeting enrollment targets, but protocol deviations are increasing, TMF documents are arriving late, and site performance is becoming inconsistent. The CRO insists these are isolated issues.* • Which signals would trigger further investigation? • How do you determine whether the issue is systemic? • What additional information would you request? • When does sponsor intervention become necessary?

	SCENARIO #2 **You Just Discovered that Your Vendor Has Been Using AI Without Your Knowledge** *During a routine oversight discussion, a study vendor discloses that an AI-enabled tool has been supporting study activities for months. The tool appears to be performing as intended, but its use was never formally communicated, reviewed, or included in sponsor oversight plans.* • Would your current oversight model have identified the use of the tool? • What questions would you ask before becoming comfortable with its continued use? • How would you assess potential impacts on quality, compliance, and data integrity? • What level of transparency should sponsors expect from vendors regarding AI-enabled processes? • How should oversight models evolve as AI becomes more common across clinical trial activities? **SCENARIO #3** **Everyone Thought Someone Else Was Watching** *A study issue is discovered that impacts multiple vendors, systems, and stakeholders. During the investigation, it becomes clear that each group assumed another team was responsible for oversight of the affected process.* • How do these gaps emerge despite documented roles and responsibilities? • What signals indicate ownership and accountability may be unclear? • How should sponsors evaluate oversight across interconnected processes? • What governance mechanisms help prevent "shared responsibility" from becoming "no responsibility"? • What would you change to reduce the likelihood of a similar issue occurring in your organization?
1:00 PM	Day Concludes

Tuesday, July 28 – Risk Management	
10:00 AM ET	**Welcome and Review of Day One**
10:15 AM	**ARE YOU FOCUSED ON THE RIGHT RISKS?** *Use Critical to Quality Factors to Separate Risks from Operational Noise* • Define meaningful Critical to Quality Factors for their studies • Differentiate critical risks from routine operational issues • Prioritize oversight activities based on impact and risk • Focus limited resources where they can have the greatest effect • Strengthen risk management through a CTQF-driven approach
10:45 AM	**ARE YOU WATCHING THE RIGHT RISK SIGNALS?** *Use Key Risk Indicators to Detect Emerging Risks Earlier and Drive More Proactive Decisions*

	• Identify Key Risk Indicators that provide meaningful insight into study performance • Distinguish actionable risk signals from routine operational noise • Connect KRIs to Critical to Quality Factors and study objectives • Establish escalation thresholds that support timely intervention • Use risk signals to drive more proactive oversight and decision-making
11:15 AM LIVE ONLY NO REPLAY	**LIVE AND UNFILTERED: SPEAKER Q&A SESSION** *Get face-to-face (virtually) with the previous speakers in an exclusive, live-only Q&A. This is your chance to ask the real questions—the ones you've been dying to ask but never see on a slide.* *No slides. No recordings. No judgment. Just candid conversation, behind-the-scenes insights, and the space to dig into what really matters.*
11:30 AM	**PANEL DISCUSSION: MAKING RISK MANAGEMENT WORK** *Why Do Important Risks Still Get Missed?* Hear directly from industry leaders as they share first-hand experiences, lessons learned, and practical strategies for addressing today's most pressing clinical trial challenges. Panelists discuss: • Why important risks still get missed despite risk assessments, KRIs, and governance processes • The signals that tell them a risk is becoming more significant than originally anticipated • How they decide when intervention is warranted—and when it isn't • Where disagreements most often occur when prioritizing risk • What they learned from risks that were underestimated, overlooked, or recognized too late
12:15 PM LIVE ONLY NO REPLAY	**INTERACTIVE ACTIVITY: RISK MANAGEMENT ROUNDTABLES** *Sharing Experiences, Lessons Learned, and Practical Approaches* *Every organization approaches risk management differently. Explore how your peers are defining, prioritizing, and responding to risk in today's clinical trial environment.* Choose a topic from the list below and come prepared to share your experiences as well as learn from others: **Roundtable #1: We Had the Risk Identified...So Why Was Everyone Surprised?** • When have risks been documented but not fully appreciated? • What causes organizations to underestimate known risks? • How do you keep critical risks visible throughout the study lifecycle? • What lessons have you learned from risks that escalated unexpectedly? **Roundtable #2: When Everything Is a Priority, Nothing Is a Priority** • How do you prevent risk registers from becoming wish lists? • What criteria actually drive prioritization decisions?

	• How do you push back when every stakeholder believes their risk is critical? • What approaches have helped focus attention where it matters most? **Roundtable #3: The Risk Data Says One Thing. The Team Says Another.** • What happens when metrics, experience, and intuition point in different directions? • Which signals do you trust most when making risk-based decisions? • How do you challenge assumptions without creating friction? • How do you make decisions when the "right" answer isn't clear?
1:00 PM	Day Concludes

Wednesday, July 29 – Trial Master File	
10:00 AM ET	**Welcome and Review of Day One**
10:15 AM	**OPERATIONALIZING THE TMF STANDARD MODEL** *Driving Consistency, Oversight, and Inspection Readiness Through Trial Master File (TMF) Standardization* • Translate TMF Standard Model concepts into practical TMF processes and workflows • Align study teams, vendors, and technology platforms around a common framework • Improve consistency across studies, programs, and organizations • Identify adoption and change management challenges before they impact TMF quality • Leverage standardization to strengthen oversight, TMF health, and inspection readiness
10:45 AM	**RISK-PROPORTIONATE TMF OVERSIGHT** *Prioritizing Review, Oversight, and Resources Where They Matter Most* • Apply risk-based principles to TMF oversight and management activities • Identify TMF records, processes, and quality indicators that have the greatest impact on inspection readiness • Prioritize review efforts based on study-specific risks and critical processes • Distinguish critical TMF issues from lower-risk administrative findings • Use TMF insights to support proactive oversight and decision-making
11:15 AM LIVE ONLY NO REPLAY	**LIVE AND UNFILTERED: SPEAKER Q&A SESSION** *Get face-to-face (virtually) with the previous speakers in an exclusive, live-only Q&A. This is your chance to ask the real questions—the ones you've been dying to ask but never see on a slide.* *No slides. No recordings. No judgment. Just candid conversation, behind-the-scenes insights, and the space to dig into what really matters.*
11:30 AM	**PANEL DISCUSSION: FALSE TMF CONFIDENCE** *How to Recognize the Difference Between Confidence in Your TMF and True Inspection Readiness*

	Hear directly from industry leaders as they share first-hand experiences, lessons learned, and practical strategies for addressing today's most pressing clinical trial challenges. Panelists discuss: • Why complete TMFs still generate inspection findings • The warning signs they wish they had recognized sooner • The metrics they trust—and the ones that create a false sense of security • What inspectors see that sponsors, CROs, and sites often miss • How they know when a TMF is truly inspection ready
12:15 PM LIVE ONLY NO REPLAY	**INTERACTIVE ACTIVITY: TMF CONFESSIONS** *Lessons Learned from TMFs Past* *Every TMF tells a story. Some stories end with successful inspections, smooth audits, and lessons worth repeating. Others involve surprises, missed warning signs, and hard-earned experience.* *Join your peers for an honest discussion about the successes, mistakes, challenges, and "I wish I had known that sooner" moments that shaped how they approach TMF oversight today.* Participants will select a facilitated discussion focused on one of the following topics: **Discussion 1: We Thought We Were Inspection Ready** • Inspection findings that caught teams off guard • The warning signs that were missed, ignored, or underestimated • Assumptions that created a false sense of readiness • What participants would do differently if they had a second chance **Discussion 2: The Metrics Told One Story. The TMF Told Another.** • When TMF metrics failed to reveal underlying issues • The indicators participants trust most—and the ones they don't • Hidden risks that weren't reflected in dashboards and reports • Lessons learned from relying on the wrong signals **Discussion 3: If I Could Start That Study Over Again** • Decisions participants would make differently today • Oversight challenges across sponsors, CROs, vendors, and sites • The mistakes that taught the most valuable lessons • Practical advice for avoiding common TMF pitfalls
1:00 PM	Day Concludes

Thursday, July 30 – Future-Ready Clinical Operations

10:00 AM ET	**Welcome and Review of Day One**
10:15 AM	**AI LITERACY FOR CLINICAL RESEARCH PROFESSIONALS** *Building the Foundation for Informed AI Decision-Making* • Understand common AI concepts, terminology, and technologies used in clinical research • Differentiate between AI capabilities, limitations, and appropriate use cases • Recognize where human expertise, oversight, and critical thinking remain essential • Understand the potential impact of AI on Clinical Operations, Quality, TMF, and Compliance activities • Build confidence in evaluating AI opportunities, risks, and vendor claims
10:45 AM	**FROM AI LITERACY TO BUSINESS VALUE** *Translating AI Understanding into Meaningful Clinical Research Opportunities* • Identify the characteristics of high-value AI opportunities • Evaluate AI initiatives based on business value, operational impact, and risk • Distinguish AI opportunities from problems that require different solutions • Recognize the organizational capabilities needed for successful AI adoption • Build a practical framework for prioritizing AI initiatives
11:15 AM LIVE ONLY NO REPLAY	**LIVE AND UNFILTERED: SPEAKER Q&A SESSION** *Get face-to-face (virtually) with the previous speakers in an exclusive, live-only Q&A. This is your chance to ask the real questions—the ones you've been dying to ask but never see on a slide.* *No slides. No recordings. No judgment. Just candid conversation, behind-the-scenes insights, and the space to dig into what really matters.*
11:30 AM	**PANEL DISCUSSION: BEYOND THE HYPE** *What Every Clinical Team Needs to Know Before Saying Yes to AI* Hear directly from industry leaders as they share first-hand experiences, lessons learned, and practical strategies for addressing today's most pressing clinical trial challenges. • The assumptions organizations get wrong about AI • What separates meaningful AI opportunities from expensive distractions • The questions they ask before trusting an AI-enabled process • The risks and governance considerations that are often overlooked • What they would advise a Clinical Operations leader evaluating AI today
12:15 PM LIVE ONLY NO REPLAY	**INTERACTIVE DISCUSSION: AI IN PRACTICE** *Sharing Experiences, Questions, and Lessons Learned* *Every organization is trying to determine how AI fits into clinical research. Join your peers for an open discussion on the opportunities, concerns, and questions shaping responsible AI adoption.*

	Choose from one of two discussions: **Table 1: Where Are You Seeing Real Value from AI?** • Which use cases are delivering measurable benefits? • Where has AI fallen short of expectations? • What makes an AI implementation successful? • How are organizations measuring value and impact **Table 2: Preparing People for an AI-Enabled Future** • How are organizations building AI literacy and readiness? • What change management challenges are emerging? • How do you maintain critical thinking while leveraging AI tools? • What new skills and capabilities will Clinical Operations teams need? • How are leaders balancing innovation with workforce adoption?
1:00 PM	Day Concludes

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