BEYOND CLINICAL COMPLIANCE

RISK, QUALITY, AND INNOVATION IN THE R3 ERA

Hybrid Event | May 12-13 in Philadelphia and Virtually

Clinical research is evolving—and so are the expectations for compliance. *Beyond Clinical Compliance* is a working conference for quality, operations, and compliance professionals who are **ready to think differently about risk, oversight, and inspection readiness in the era of ICH E6(R3)**.

This event goes beyond frameworks and checklists. It **creates space for real conversations and shared problem-solving across roles and organizations**. Whether you're managing trials, overseeing vendors, optimizing systems, or building inspection readiness strategies, you'll leave with actionable insights and renewed focus. Click here for more details and to register.

Cut through the noise.	*Get clarity on E6(R3), AI, and smarter oversight.*
Find your people.	*Real talk, shared challenges, honest solutions.*
Leave recharged.	*With strategies you'll actually use.*
Do better—together.	*For patients. For teams. For the future.*
Trust the source.	*Backed by 20 years of industry intelligence.*

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Agenda

Tuesday, May 12 – Main Conference Day One	
8:00 AM ET	**Registration and Networking Breakfast**
9:00 AM ET LIVE STREAM	**Conference Welcome and Opening Remarks** *Kristen Hunter, Event Director, KH CONFERENCES*
9:30 AM ET LIVE STREAM	**INSIDE THE CLINICAL TRIAL** **What the Patient Experience Reveals About Trust, Communication, and Trial Design** *Kate Korson, Clinical Trial Participant; Patient Advocate, PENN MEDICINE* *Wil Vickroy, Clinical Research Nurse, UNIVERSITY OF PENNSYLVANIA* • Hear a firsthand account of what it **feels like to participate in a clinical trial** • Understand how trial design, communication, and operational decisions are experienced from the patient perspective • Explore **what builds, or erodes, patient trust** during the clinical trial journey • Reconnect clinical quality, compliance, and operations work to the individuals the trials are ultimately designed to serve
10:00 AM ET LIVE STREAM	**Keynote Q&A with In-Person and Virtual Audiences**
10:15 AM ET	**Networking and Refreshment Break**
10:45 AM ET LIVE STREAM	**CHAMPIONS OF QUALITY** **They Built the Culture Behind Compliance: How Quality Leaders Create Environments Where the Right Decisions Actually Happen** **Moderator** *Dawn Lundin, Quality Head; Adjunct Professor*

	Panelists *Teresa DeVincentis, Quality Head, SOLID BIOSCIENCES* *Ruth Ann Subach, Vice President, Clinical Development & Operations, FUJIFILM PHARMACEUTICALS* *Melissa Suprin, Head, Risk-Based Quality Management, BEONE MEDICINES* *Stefan van den Akker, Head of R&D Quality Risk Management, ACADIA PHARMACEUTICALS* • Explore **how strong quality cultures are built** across clinical, operations, and functional teams—not just within QA • Identify the behaviors, signals, and leadership actions that indicate whether quality is **truly embedded or just procedural** • Understand how leaders influence decision-making in high-pressure environments where **speed and quality compete** • Examine where **quality culture most often breaks down** across CROs, vendors, and internal teams—and why • Apply practical approaches to reinforce **accountability, ownership, and proactive quality** across the trial lifecycle
11:30 AM ET 	**Panel Q&A with In-Person and Virtual Audiences**
11:45 AM ET 	**RISK TRIAGE IN COMPLEX TRIALS** **When Everything Looks Like Risk: How Clinical Quality Teams Can Triage Oversight in Complex Trials** *Donna Dorozinsky, Founder & CEO, JUST IN TIME GCP* • Recognize where trial complexity creates the **greatest oversight risk** across vendors, systems, and processes • **Prioritize the critical-to-quality factors** most likely to affect patient safety and data integrity • **Differentiate meaningful risk signals from operational noise** in complex trial environments • **Target oversight** where it will have the greatest impact on compliance and inspection readiness • Use a **practical triage framework** to manage complexity without overwhelming quality teams

12:15 PM ET 	**Speaker Q&A with In-Person and Virtual Audience**
12:30 PM ET	**Conclusion of Virtual Experience**
12:30 PM ET	**Lunch for In-Person Audience**
1:30 PM ET	**CASE STUDY: SUPPLIER QUALIFICATION** **Peeling Back the Layers: How Risk-Based Supplier Qualification is Changing Clinical Oversight** *Daniel Khordi, Executive Director, MRL Quality Assurance, MERCK* • Apply risk-based approaches to qualify clinical service providers across an expanding vendor ecosystem • Identify where supplier capabilities, technology claims, and operational realities often diverge • Evaluate how quality teams are using **data signals, KPIs, and governance models** to monitor supplier performance • Examine lessons learned from implementing a global supplier qualification program across evolving trial services • Strengthen Quality's role in supplier selection, qualification, and ongoing oversight
2:15 PM ET	**INTERACTIVE CROWD-SOURCE: OPERATIONALIZING RBQM** **How Do YOU Decide What Actually Deserves Oversight?** *Melissa Suprin, Head, Risk-Based Quality Management, BEONE MEDICINES* ICH E6(R3) reinforces risk-proportionate oversight and Quality by Design, but translating these principles into operational workflows is still a challenge. In this interactive session, we turn to the experienced experts in the room to explore how teams are actually implementing risk-based quality management (RBQM) in practice. • How are you defining **critical-to-quality factors** when everything appears to carry risk? • How do you establish **risk thresholds and escalation triggers** that teams actually follow? • What activities are you monitoring **centrally versus on-site**, and why? • How are you documenting **risk decisions and oversight rationale** in a way that holds up during a clinical inspection?

	No slides. No theory. Just real strategies and shared experience from clinical pros doing the work.
2:45 PM ET	**Networking and Refreshment Break for In-Person Audience**
3:15 PM ET	**CROSS-FUNCTIONAL OVERSIGHT** **When Everyone Owns the Risk, No One Does: The Reality of Cross-Functional Oversight** *Reetu Dandora, Senior Vice President, Quality and Regulatory Compliance, AVEO ONCOLOGY* *Abby Statler, PhD, Senior Director, Clinical Quality Assurance, AVEO ONCOLOGY* In today's complex clinical trial environment, oversight is shared across clinical operations, safety, quality, data management, regulatory, and external partners. Yet when critical issues arise, decision rights and risk ownership are often unclear - leading to delayed action, fragmented responses, and increased inspection risk. This session will explore the uncomfortable reality that while oversight is distributed, accountability is not always clearly defined. • Examine where cross-functional oversight **most frequently breaks down** - and why • Challenge common assumptions around **shared ownership vs. true accountability** • Define practical approaches to **clarifying decision rights** across functions and vendors Participants will leave with actionable strategies to ensure that when risks emerge, they are not just identified - but clearly owned, addressed, and defensible during inspection.
4:00 PM ET	**PANEL: SCALING CLINICAL OVERSIGHT AND SUPPORT** **Your Team Can't Do Everything: How Leaders are Expanding Expertise Without Slowing Trials** *Moderator – Leila Cupersmith, Fractional Sponsor-Side Clinical Operations Oncology Leader; CEO, CHOICE CLINOPS* *Panelists* *Gaby Graterol, Associate Director, Clinical QA, ASTELLAS* *MyLe Hoang, Head of North America and EU Clinical Quality Assurance, EISAI* *Maryann Livolsi, Senior Director, GCP Quality Assurance, BILL AND MELINDA GATES RESEARCH FOUNDATION*

	• Examine where clinical teams most often experience **resource strain during the trial lifecycle**, from startup through inspection readiness • Compare the advantages and limitations of **hiring full-time staff versus bringing in external expertise** • Explore hybrid resourcing models that expand capabilities across **quality, documentation, oversight, and inspection readiness** • Discuss when consulting support accelerates progress—and when it creates **new coordination challenges** • Identify how leaders are structuring flexible support models that strengthen oversight **without slowing trial execution**
4:45 PM ET	**ROUNDTABLE DISCUSSIONS: CHOOSE YOUR TOPIC** **Informal Discussion with Like-Minded Quality-Driven Clinical Professionals on the Topic of Your Choice** *Engage in an intimate and informal discussion on several of the topics below.* 1. **TRIAL GOVERNANCE** Demonstrating Trial Governance and Control During Regulatory Inspections 2. **DOING MORE WITH LESS** Building Quality and Oversight in Small Clinical Teams 3. **VENDOR OVERSIGHT REALITIES** Oversight vs. Control: How Much Should Sponsors Really Be Doing? 4. **QUALITY IN DECENTRALIZED / HYBRID TRIALS** Oversight When the Trial Isn't In One Place 5. **CAREER & INFLUENCE IN CLINICAL QUALITY** From Compliance Enforcer to Strategic Partner
5:30 PM ET	**Booze and Schmooze / Mock and Talk Reception** *Have a drink and enjoy some refreshments as we casually discuss today's learnings and catch up with old friends.*
6:30 PM	Day Concludes

Wednesday, May 13 – Main Conference Day Two

8:30 AM ET	**Registration and Networking Breakfast**
9:00 AM ET	**Welcome to Day Two** *Kristen Hunter, Event Director, KH CONFERENCES*
9:15 AM ET	**PANEL: AI AND INNOVATION RISKS** **Leveraging Innovative Technologies to Drive Efficiency Without Creating New Compliance Risks** *Moderator: Aaron Grant, Head of Innovation, JUST IN TIME GCP* *Panelists* *Bill McDonald, Quality Business Partner, Data & Digital, R&D Quality & Risk Management, GSK* *Olga Rostovtseva, Associate Director, GxP Quality, AMGEN* • **Examine where AI and advanced analytics are already improving** clinical quality, documentation review, and trial oversight • **Identify where innovation can introduce** new compliance and governance risks • **Explore how organizations are implementing AI-enabled tools** while maintaining human oversight and accountability • **Discuss governance models that ensure AI and analytics remain** transparent, traceable, and defensible • **Apply practical approaches for balancing** innovation, efficiency, and regulatory expectations
10:00 AM ET	**BRIDGING THE OVERSIGHT GAP** **When Oversight Breaks Down: Real Scenarios That Test Operational and Quality Alignment** *Michele Weitz, Principal, GCP VISION CONSULTING* • Walk through **real-world scenarios** where operational execution and quality oversight fall out of sync • Identify **early risk signals** across study execution, data, and documentation—not just in the TMF • **Clarify ownership of oversight decisions** across sponsors and partners • Examine how **breakdowns impact evidence of control** during GCP inspections

	• Apply practical strategies to **align operations, quality, and decision-making** in real time
10:30 AM ET	**Networking and Refreshment Break**
11:00 AM ET	**REGULATORY DISRUPTIONS** **FDA's New Inspection and AI Pilot Programs: What Sponsors Need to Understand Now** *Prachi Narayan, MD, Oncology Research & Clinical Trials Expert* • Review FDA's newly announced **one-day inspectional assessment pilot** and its use of risk-based screening approaches • Examine how FDA is **evaluating AI-enabled technologies** in early-phase clinical trials, including recruitment, safety monitoring, and dose escalation • Explore FDA's **Real Time Clinical Trials (RTCT) initiative** and how this changes inspection readiness • Discuss the questions these initiatives raise for sponsor oversight, inspection readiness, and future clinical operating models under ICH E6(R3)
11:30 AM ET	**INTERACTIVE CROWD-SOURCE: GCP INSPECTION GOSSIP** **What Teams Have Experienced During Recent Inspections—and How They Are Adapting in a Time of Change** This is not a panel. This is a room full of experience, and we are going to use it. In this interactive session, we will tap directly into the collective knowledge of attendees who have faced GCP inspections and those preparing for them. You will not just hear stories. You will challenge them, question them, and learn what holds up under scrutiny. • **Step into real inspection moments** by hearing firsthand accounts of what regulatory investigators actually asked for, pushed on, and did not accept • **Compare expectation vs. reality** by reacting to those experiences from the perspective of teams still preparing • **Surface where teams struggle most** when explaining oversight, data flow, and decision-making under pressure • **Identify what signals control** versus what raises concern during live inspection interactions • **Walk away with practical insight** on how to prepare for conversations you cannot script

	This session is built entirely from the experience in the room. No slides. No rehearsed answers. No generic advice. What happens here will not be repeated anywhere else.
12:30 PM ET	**Close of Main Conference / Lunch for In-Person Attendees**
	HANDS-ON INTERACTIVE WORKSHOP
1:30 PM ET	**RISK-PROPORTIONATE OVERSIGHT** **Building a Defensible Risk-Proportionate Oversight Model for Complex Clinical Trials** *Leslie Sam, President, LESLIE SAM AND ASSOCIATES, LLC* ICH E6(R3) reinforces the expectation that trial oversight should be **risk-proportionate, focused on what matters most for patient safety and data integrity.** Yet many organizations still struggle to translate these principles into operational oversight models that are clear, consistent, and defensible during inspections. In this interactive workshop, participants will work through practical scenarios and structured exercises to design an oversight approach that aligns oversight activities with real trial risk. **In this workshop, you will:** • Define **critical-to-quality factors** and link them to oversight priorities across vendors, systems, and processes • Distinguish meaningful **risk signals from operational noise** when everything appears to carry risk • Map how risk assessments translate into **specific oversight activities and governance structures** • Determine what documentation demonstrates **risk-proportionate decision-making during inspections** • Build a practical framework for applying **risk-proportionate oversight across complex trial environments** Participants will leave with a **structured oversight model they can adapt within their own organizations** to align oversight effort with trial risk while maintaining clear inspection defensibility.
5:00 PM ET	**Workshop and Conference Concludes**

REGISTRATION DETAILS

Attend in person to experience the full event—every session, every connection, and every opportunity to engage. Gain fresh perspective, practical tools, and the inspiration to lead with clarity in the R3 era.

Can't attend in person? You can still be part of the event. Join virtually to live-stream select sessions and engage with the full community through the event app.

THE IN-PERSON EXPERIENCE

*Take two days to be with your people— leave **inspired, motivated, and reconnected to your purpose** of driving quality in clinical research.*

Pharma / Biotech / Device Companies	**$1,299**
General Registration (CROs, Service & Tech Providers, Consultants)	**$1,599**

Add $250 for a Post-Conference Workshop on Risk-Proportionate Oversight

THE VIRTUAL EXPERIENCE

Can't join us in-person?
Live-stream select sessions on May 12, ask questions in real time, and connect with the full audience through the event app—with on-demand access after the event.

Pharma / Biotech / Device Companies	**$299**
General Registration (CROs, Service & Tech Providers, Consultants)	**$599**

Cross-Functional Alignment is Critical - Send a Team Contact for Group Discounts

THE IN-PERSON EXPERIENCE

Join us in Philadelphia for the full experience—every session, every connection, every opportunity to shape what's next.

- **Dates and Timing**
  - Tuesday, May 12, 8:00 AM ET – 6:30 PM ET
  - Wednesday, May 13, 8:30 AM ET – 1:30 PM ET
    - Optional Post-Conference Workshop 1:30 PM ET – 5:00 PM
- **Location**
  - CYTO|PHYL @ Cira Centre, 2929 Arch Ste 250, Philadelphia, PA 19104

- **Accommodations**
  - The event space is not part of a hotel, so please secure your own accommodations if needed.
    - The following locations are all within walking distance to the event venue
      - The Study at University City – 0.6 mile
      - AKA University City – 0.4 mile
    - These hotels are just a short drive away

- Sonesta Philadelphia Rittenhouse Square – 0.9 mile
- The Inn at Penn, a Hilton Hotel – 1 mile

- **In-Person Pricing**
  - Pharma/Biotech/Device Company Registration
    - Main Conference - $1,299
    - Post-Conference Workshop + $250
  - General Registration
    - Main Conference - $1,599
    - Post-Conference Workshop + $250

- **What does that Include?**
  - Two days out of the office to be face to face with like-minded peers and walk through common challenges and leave inspired and motivated to take action and make change.
  - In-Person access to all sessions and presentations listed in agenda
    - PDF versions of all slides presented, pending speaker approval
    - Your choice of roundtable discussion
    - Optional post-conference workshop add-on
  - All networking breaks and Booze and Schmooze/Mock and Talk Reception
  - Breakfast, lunch and ample snacks and beverages for the duration of the conference
  - Access to the conference app for pre, during, and post event engagement with entire audience (both in-person and virtual)
  - On-demand access to the live-streamed sessions via the conference app

THE VIRTUAL EXPERIENCE

Can't attend in person? Stream selected sessions live and engage with the full community—on your schedule, from anywhere.

- **Dates and Timing**
  - Live Stream Access – Real-Time Engagement with Speakers and In-Person Audience
    - Tuesday, May 12, 9:00 AM ET – 12:30 PM ET
  - On-Demand Access to Streamed Sessions – Available shortly following session conclusion through conference app

- **Virtual Pricing**
  - Pharma/Biotech/Device Company Registration - $299
  - General Registration - $599

- **What does that Include?**
  - Live-stream access to select main stage sessions on May 12
  - Real-time participation in Q&A and chat during live-streamed sessions
  - On-demand access to all streamed sessions via the conference app after the event
  - Access to the conference app for pre-, during-, and post-event engagement with the full audience (in-person and virtual)
  - Downloadable session slides (PDFs) from streamed presentations, pending speaker approval

Questions? Comments?
Contact Kristen Hunter at kristen@khconferences.com