Inspection Readiness 360°

MOMENTUM Events

JANUARY **27-28, 2026**

convene™ PHILADELPHIA, **PA**

Align Clinical Operations, TMF, and Quality Systems in the Era of ICH E6(R3) Through Process and Systems to Ensure Inspection Readiness

FEATURED SPEAKERS

Rebecca Bichard
Director, Clinical Process Excellence and Training
insmed

Ashley Cafasso
Associate Director, Audit Management
Apellis

Soyoung Chong
Principal Quality Lead
Genentech

Sarah Zrout
Director, Research & Development Quality
Replimune

Dawn Lundin
Vice President, Global Quality Executive Leader

Nancy Wintering, LCSW, CCRP
Assistant Director
Thomas Jefferson University

Mark Behn
Senior Director, Clinical Systems Quality
AstraZeneca

Vinay Edwin
Director, Clinical Quality Lead
PHARVARIS

Aryn Knight
Associate Vice President, Clinical Research
MEMORIAL HERMANN

Jamie Marie Toth
Senior Director Trial Master File Management & Records
BeOne

Loreena Sadowski
Senior Director, RDQ GCP Inspection Management
Bristol Myers Squibb

Niloy Shah
Executive Director, Research & Development Quality
Replimune

Angela Teliha
TMF Operations and Process Excellence Advisor

Robert Staszewski
Associate Director, Clinical Oversight & Systems
United Therapeutics CORPORATION

Andre Morais Campos
Senior Vice President, Global Clinical Operations
ILiAD BIOTECHNOLOGIES

Monika Joshi
Endowed Professor in Cancer Clinical Investigation
PennState Cancer Institute

Grace Crawford
Executive Director, Clinical Operations Quality & Learning
AstraZeneca

Reetu Dandora
Senior Vice President, Quality and Regulatory Compliance
AVEO ONCOLOGY

Matt Lowery
CEO and Principal Consultant
PG THE PATHWAYS GROUP

Maureen Cunningham
Senior Director
United Therapeutics CORPORATION

Judyth Zahora, PMP
Executive Director, Quality Assurance
TYRA

Samelyse Lees
Manager, Clinical Development & Policy
GSK

Priya Chaturvedi
Vice President, Head of Global Clinical Quality
Eisai

David Vulcano, LCSW, MBA, CIP, RAC, FACRP
Vice President, Clinical Research Compliance & Integrity
HCA Healthcare

Teresa Gorecki
VP and Practice Director
COMPLIANCE ARCHITECTS

Kathleen Frenia Cohen, PharmD
Senior Vice President, Clinical Development Operations
avalo THERAPEUTICS

Adriana Robinson
Manager, Global TMF
BeOne

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EVENT EXPERIENCE & BENEFITS

24+
Industry leaders on our speaking faculty!

Hear from
7+
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4+
Case Studies

7+
Hours of Networking Opportunities

Interactive Discussions
Thought Provoking Panels

A Practical Walkthrough of How Organizations Are Evolving Under ICH E6(R3)

YOUR INVITATION FROM THE EVENT PRODUCER

Welcome to the Inspection Readiness 360 Summit, taking place January 27-28, 2026 in Philadelphia! We're thrilled to have professionals from study startup, clinical operations, document management, TMF governance, quality assurance, and regulatory affairs all together for what promises to be an invaluable few days. In our evolving landscape, inspection readiness must be woven into every part of the clinical trial lifecycle—from study design through closeout. With the release of ICH E6(R3), organizations must reassess and strengthen their approaches to Trial Master File (TMF) practices, document governance, and cross-functional coordination. This summit will help you align processes, embed a culture of continuous readiness, and ensure your organization and external partners stay audit-ready and audit-resilient.

Over the course of this event, you'll gain actionable insights, real-world strategies, and practical tools—whether you manage TMF, oversee document control, or support compliance across functions. You'll hear from peers, walk away with new frameworks, and build connections that reinforce readiness as an everyday mindset. Expect to walk away empowered to enhance inspection preparedness from day one and throughout your trials.

Scott Grossman
Chief of Content
MOMENTUM Events

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DAY ONE | Tuesday, January 27, 2026

7:45 am **Registration Opens and Networking Breakfast**

8:45 am **Opening Remarks**

9:00 am Align Processes and Systems to Build a Culture of Inspection Readiness

- Align clinical, quality, and regulatory teams around a centralized inspection readiness strategy
- Build end-to-end visibility through system integration, ensuring consistency across TMF, CTMS, and quality platforms
- Use process mapping and ownership models to reduce ambiguity and ensure accountability across teams

Priya Chaturvedi
Global Vice President, Clinical Quality Assurance
EISAI

9:45 am Drive Real Change for ICH E6(R3): Going from Strategy to Actually Adaptation

- Overview of the ICH E5 (R3) and the impact on your clinical process and changes needed
- Lessons from transitioning from a global quality leadership role into site management and monitoring
- Building a scalable site engagement model: insights from regional outreach, readiness assessments, and awareness campaigns
- Practical takeaways from global site engagement on the impact of R3

Grace Crawford
Executive Director, Clinical Operations Quality & Learning
ASTRAZENECA

Mark Behn
Senior Director, Clinical Systems Quality
ASTRAZENECA

10:30 am Beyond the Noise: Identify Real Risk to Protect Your Trial

- How to build processes that ensure both data integrity and regulatory compliance from study startup through closeout
- What regulators actually care about—and what findings can derail a site, trial, or even product approval
- Strategies for empowering site teams, investigators, and clinical staff to focus on what matters most
- How to differentiate between “nice to have” and “need to have” in your inspection readiness strategy

Lorenna Sadowski
Senior Director, RDQ GCP Inspection Management
BRISTOL MYERS SQUIBB

11:15 am **Networking Break**

11:45 am Clinical Leaders Panel: Embedding Compliance into Clinical Operations Decision-Making as a Foundation for Inspection Readiness

- Explore how Clinical Operations leaders embed inspection readiness into decision-making across the study lifecycle
- Discuss strategies for balancing timelines, resources, and quality while maintaining GCP compliance
- Examine cross-functional collaboration with Quality, TMF, and Medical teams to support continuous inspection readiness

André Campos
Senior Vice President, Global Clinical Operations
ILIAD BIOTECHNOLOGY

Rebecca Bichard
Clinical Process Excellence and Training
INSMED

Brian Dean
Vice President, Clinical Operations
GAMETO

Teresa Gorecki
VP and Practice Director
COMPLIANCE ARCHITECTS

DAY ONE | Tuesday, January 27, 2026

12:45 pm **Networking Lunch**

1:45 pm **Site-Level Inspection Readiness: Empowering Teams, Systems, and Standards to Ensure High Quality and Impactful Sponsor/ Site Relationship**

- How clinical sites can proactively prepare for FDA, sponsor, and internal audits
- Strategies for training site staff on GCP, documentation practices, and inspection protocols
- Leverage technology (eISF, eLogs, CTMS, TMF) to streamline access to essential documents

Monika Joshi, MD, MRCP
Professor of Medicine
PENN STATE CANCER INSTITUTE

Nancy Wintering, LCSW, CCRP
Assistant Director
THOMAS JEFFERSON UNIVERSITY

David Vulcano, LCSW, MBA, CIP, RAC, FACRP
Vice President, Clinical Research Compliance & Integrity
HCA HEALTHCARE

2:15 pm **CASE STUDY: Impacting a Site to Maintain Inspection Readiness**

- Focused on site partnership over policing, emphasizing collaboration rather than audits
- Used metrics-driven quality management to proactively identify and resolve documentation gaps
- Developed a behind-the-scenes TMF process with a single-owner, integrated data structure

Niloy Shah, MS
Executive Director, Research & Development Quality
REPLIMUNE

Sarah Zout
Director, Research & Development Quality
REPLIMUNE

3:00 pm **Networking Break**

3:30 pm **Case Study: Utilizing Mock Inspections to Impact Global Sponsor and Site Inspections**

- A 360-degree inspection readiness strategy was implemented to align teams, documents, and systems across both sponsor and site inspections, ensuring all aspects of preparation were accounted for before regulators arrived.
- The presenter played a central role in leading mock inspections and interviews, helping study teams prepare for real-world scenarios through role-playing exercises and targeted feedback.
- Overview of a llive FDA site inspection in South Korea, she supported the team in the backroom, managing document requests, tracking communication with global team, and ensuring timely responses to inspector needs.

Soyoung Chong
Principal Quality Lead, Quality Assurance Programs
GENENTECH, A MEMBER OF THE ROCHE GROUP

4:15 pm **ISF Reference Model: Strengthening Site-Level Inspection Readiness in Alignment with ICH E6(R3)**

- Understand the purpose and structure of the ISF (Investigator Site File) Reference Model and how it aligns with ICH E6(R3) expectations
- Explore how standardizing site documentation supports inspection readiness across sponsors, CROs, and sites
- Identify key components of the ISF Reference Model that contribute to data integrity, audit trails, and GCP compliance

Jamie Marie Toth
Senior Director, Global TMF Management & Records
BEONE MEDICINES

Matt Lowery
CEO and Principal Consultant
THE PATHWAYS GROUP

Aryn Knight
Associate Vice President, Clinical Research
MEMORIAL HERMANN HEALTH SYSTEM

5:15 pm **Cocktail Reception**

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DAY TWO | Wednesday, January 28, 2026

7:45 am **Registration Opens and Networking Breakfast**

8:45 am **Day Two Opening Remarks**

9:00 am CASE STUDY: Building a Resilient Inspection Readiness Framework

- From Setback to Strength: Rebuilding inspection readiness after a challenging inspection using QRBM, SOP optimization, and mock inspections
- Real-Life Lessons: Insights from Regulatory inspections during live clinical trials

Maureen Cunningham
Senior Director
UNITED THERAPEUTICS

9:45 am PANEL: Build a TMF Oversight Framework That Supports your Clinical and Inspection Process

- Learn how to design dashboards that track TMF health, document status, and milestone progress in real time
- Explore how to integrate manual oversight with automated tools to maintain TMF quality and compliance
- Understand how to train internal teams to own and execute TMF responsibilities confidently and consistently
- Discover strategies to build a TMF process that aligns with your organizational workflows and regulatory expectations

Adriana Robinson
Manager, Global TMF
BEONE

Angela Teliha
TMF Operations and Process Excellence Advisor

10:30 am Inspection Steady Panel: Staying Ready Through Systems, Technology & Processes in an R3 World

- Establish a State of “Inspection Steady”: Creating simple, scalable processes and systems that maintain constant readiness rather than scrambling before inspections
- Define what Inspection Readiness is to your organization
- Optimize Oversight Through CTMS and Analytics: Using clinical trial management systems and real-time data analytics to identify study hotspots, site-level risks, and trends that require proactive intervention.

Robert Staszewski
Associate Director, Clinical Oversight & Systems
UNITED THERAPEUTICS

Vinay Edwain
Director, Clinical Quality Lead
PHARAVIS

Reetu Dandora
Senior Vice President, Quality & Regulatory Compliance
PHARAVIS

Judyth Zahora, PMP
Executive Director, Quality Assurance
TYRA BIOSCIENCES

11:30 am **Networking Break**

12:00 pm CASE STUDY: Managing Global Inspections Through a Programmatic Approach to Roles, Process, and Readiness

- Explore how a cross-functional project management framework was used to successfully coordinate multiple global inspections across regulatory agencies.
- Learn how clearly defining inspection roles and responsibilities—both internally and with external vendors—led to streamlined communication, faster issue resolution, and motivating all parties.

Ashley Cafasso
Associate Director, Audit Management
APELLIS PHARMACEUTICALS

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DAY TWO | Wednesday, January 28, 2026

12:45 pm **Networking Lunch**

1:45 pm **From Inspection Ready to Inspection Prepared: Turning Ongoing Readiness into Confident Action**

- How to design and conduct meaningful TMF mock inspections
- Who should participate, and what should be in scope?
- Create checklists aligned with FDA/EMA expectations and ICH E6(R3)

Samelyse Lees
Manager, Clinical Development & Policy
GLAXOSMITHKLINE

2:30 pm **Practical Approach: Quality Management that Supports Regulatory Compliance**

- Explore how basic quality principles can proactively support regulatory compliance and inspection readiness across the clinical development lifecycle.
- Discover how QbD embeds quality at every phase through risk-based thinking and cross-functional collaboration.
- Learn how to include use of digital tools and data-driven approaches to streamline quality systems and improve inspection preparedness.

Dawn Lundin
Vice President, Global Quality Executive Leader

3:15 pm **Summit Concludes**

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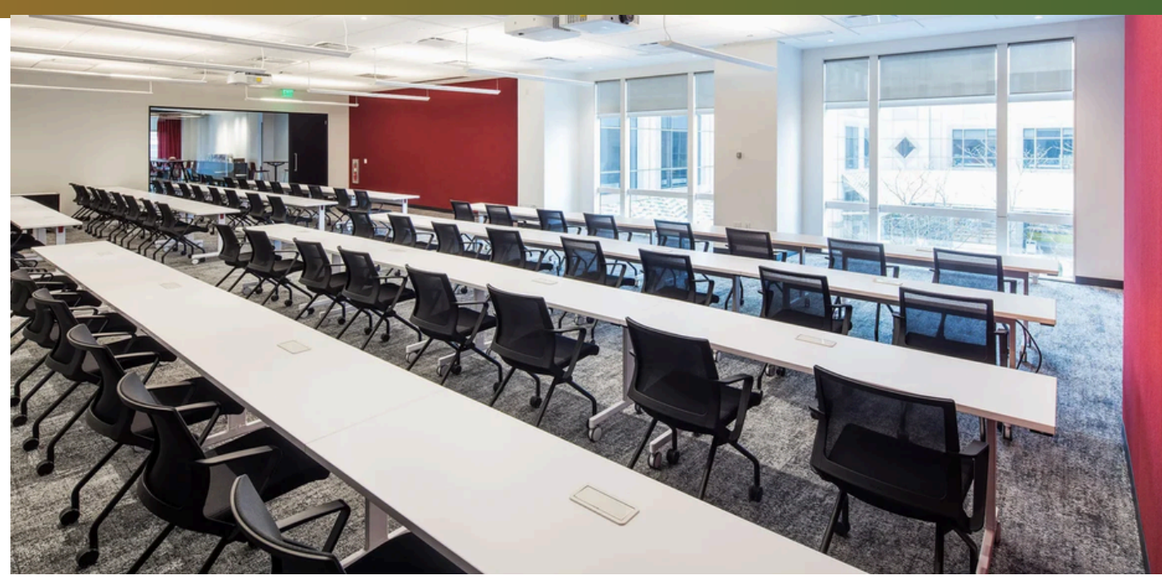

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WHY SPONSOR

Become a foundational partner in building clinical inspection readiness excellence. The Inspection Readiness 360 brings together cross-functional leaders—from TMF and Clinical Ops to Quality, Regulatory Affairs, and GCP Compliance—to collaboratively transform how inspection readiness is embedded into everyday operations

Unmatched access to decision-makers

Engage directly with inspection readiness leaders, hear challenges directly and showcase how your solutions seamlessly support compliance across the trial lifecycle

Amplified visibility across key disciplines

Position your brand at the forefront of seminars, panel discussions, and breakout sessions designed for top professionals in Clinical Operations, QA, TMF Management, Regulatory Affairs, and more

Capitalize on high-impact networking

With over 7 hours of dedicated networking, including receptions and curated sessions, your sponsorship ensures meaningful visibility and relationship-building with sponsors, CROs, vendors, and technology innovators

Demonstrate thought leadership

Stand out through custom curated engagements—from thought leadership sessions and mock inspection showcases to branded workshops—anchoring your role as an inspection readiness champion in the ICH E6(R3) era

Drive measurable ROI

Tailored sponsorship packages enable you to present your brand to a targeted and influential audience, supporting pipeline acceleration, product adoption, and long-term partnerships.

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Frank Fernandez
Sponsorship Sales Director
Frank@momentumevents.com

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