







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 Genentech



**Sarah Zrout** Director, Research & Development Quality Replimune



Maureen **Cunningham** Senior Director **≜** United Therapeutics



**Samelyse Lees** Manager, Clinical **Development & Policy** GSK



**Vinay Edwin** Director, Clinical **Quality Lead** 



**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



Judyth Zahora, Executive Director, Quality **TYRA** 



**Robert Staszewski** Associate Director, Clinical Oversight & Systems **L** United Therapeutics RPORATION



**Andre Morais Campos** Senior Vice President, Global Clinical Operations 💿 I L i A D



Monika Joshi Endowed Professor in Cancer Clinical Investigation **PennState Cancer Institute** 



**Grace Crawford** Executive Director, Clinical Operations Quality & Learning AstraZeneca 2



Senior Vice President, **Quality and Regulatory** Compliance ONCOLOGY





**Priya** Chaturvedi Vice President, Head of Global Clinical Quality



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## **EVENT EXPERIENCE & BENEFITS**











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

### YOUR INVITATION FROM THE EVENT PRODUCER

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





## 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** 

#### 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** 





## DAY ONE Tuesday, January 27, 2026

#### **Networking Lunch** 12:45 pm

Site-Level Inspection Readiness: Empowering Teams, Systems, and Standards to Ensure High 1:45 pm **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** 

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

- 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



3:30 pm

Niloy Shah, MS

Executive Director, Research & Development Quality





Case Study: Utilizing Mock Inspections to Impact Global Sponsor and Site Inspections

Sarah Zout Director, Research & Development Quality **REPLIMUNE** 

**Networking Break** 

## 3:00 pm

- 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 realworld 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** 

**Cocktail Reception** 5:15 pm





## **DAY TWO Wednesday, January 28, 2026**

7:45 am Registration Opens and Networking Breakfast

8:45 am Day Two Opening Remarks

#### 9:00 am Align Processes, Systems & Teams for Ongoing Inspection Readiness

- Learn how to build a scalable inspection readiness program by understanding the systems and developing SOP to support the technology in place.
- Integrate TMF, quality, and regulatory systems through process mapping and technology implementation
- Coordinate cross-functional readiness across clinical, medical, and pharmacovigilance teams

#### 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 & Strategy Operations Professional

## 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





## DAY TWO | Wednesday, January 28, 2026

# 12:45 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** 

1:15 pm Networking Lunch

#### 2:00 pm 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** 

#### 2:45 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

#### 3:30 pm Panel: The Future of Inspection Readiness and the Global Inspection Landscape

- How globalization, technology, and regulatory harmonization are reshaping inspection expectations
- Insights from recent FDA, EMA, MHRA, and PMDA inspections
- Preparing for hybrid and remote inspections as a long-term standard

4:30 pm Summit Concludes

#### **VENUE**

## convene.

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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

#### 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

#### 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

#### **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

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### **Frank Fernandez**

Sponsorship Sales Director Frank@momentumevents.com

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