

# CLINICAL TRIAL RISK AND PERFORMANCE MANAGEMENT SUMMIT

A METRICS CHAMPION CONSORTIUM EVENT

**KEYNOTE SESSION:**

**Tracking the Patient  
Engagement Movement  
and its Impact on Clinical  
Research Execution**



**Kenneth Getz**

Director of Sponsored Programs and Associate Professor, Tufts University; Founder and Board Chair, CISCRP

**FEATURED SPEAKERS:**

**David Anderson**

Manager, DSI

**Mary Brantner**

Senior Director, Mallinckrodt Pharmaceuticals

**Keith Dorricott**

Contractor for the Metrics Champion Consortium, Director, Dorricott Metrics & Process Improvement Limited

**Kevin Douglass**

Associate Director, DSI

**Nancy Dynes**

Metrics Consultant, Eli Lilly and Company

**Jacob Ehrlich, JD, MPH**

Owner & Principal Consultant, Pure Health Consulting

**Michael Fitzpatrick**

Associate Director, Sarepta

**SEPT. 4-5, 2019**

THE LOEWS PHILADELPHIA

**2019 SUMMIT HIGHLIGHTS**

Join the MCC Summit for an incredible program, face-to-face dialogue and in-depth discussions with the field's foremost experts. Register today to hear new presentations, panel sessions, small interactive group exercises and hands-on case studies including:

- ▣ **Secrets to implementing successful metric programs**, with four industry veterans explaining what to measure, establishing data requirements, designing easy-to-understand reports and using metrics to identify areas of concern.
- ▣ **Tracking the patient engagement movement** and its impact on clinical research execution.
- ▣ **Risk-based quality management**, an entire track focused on emerging practices, the impact of ICH-E6(R2) updates, risk management for small sponsors and developing and using a risk library. Breakout session topics:
  - Measuring centralized monitoring and site monitoring
  - Risk-based site monitoring, risk-based quality management — key risk indicators (KRIs) & quality tolerance limits (QTLs)
  - Risk management for small sponsors
  - Development and use of a risk library
  - Keeping the risk assessment up to date
  - What skills are needed by clinical research associates (CRAs) and centralized monitors with risk-based site monitoring?
  - Applying artificial intelligence/machine learning to risk-based quality management
  - Coordinating the roles of sponsor and clinical research organization (CRO) in risk-based quality management
  - Challenges of gathering information to support risk evaluation
- ▣ **Vendor Oversight**, an all-new track developed to focus on the impact of ICH E6(R2), developing healthy sponsor/vendor engagement, CRO oversight and using metrics to manage vendor risk and performance
  - Plus, an interactive small-group exercise challenges participants to uncover root causes

(continued on page 2)

**Duncan Hall**

CEO & Founder, Triumph Research Intelligence, Ltd.

**Todd Johnson**

Principal Consultant,  
Halloran Consulting Group, Inc.

**Nechama Katan**

Associate Director, Pfizer

**Olgica Klindworth**

Director, PPD

**Tom Littleton**

Director, PPD

**Maria Makarovskaya**

Senior Director, Tesaro, Inc. a GSK Company

**Arturo Morales**

Chief Technology & Data Officer,  
WCG Analgesic Solutions

**Aaron Nolan**

Consultant, Eli Lilly and Company

**Jehan Poco**

Manager, DSI

**Johann Proeve**

Chief Scientific Officer, Cytegrity

**Margaret Sabe**

Principal Consultant,  
Halloran Consulting Group, Inc.

**Sandra (SAM) Sather, MS, BSN, CCRA, CCRC**

Vice President,  
Clinical Pathways, LLC

**Dr. Oleg Shevaldyshev**

Associate Director Quality Assurance, PRA Health Sciences

**Linda Sullivan**

Co-Founder and Executive Director,  
Metrics Champion Consortium

**Ravin Warnakulasuriya**

Senior Director, Vertex Pharmaceuticals

**Liz Wool**

President,  
Wool Consulting Group, LLC

**Steve Young**

Chief Operations Officer,  
CluePoints

**DAY 1 AGENDA** — Wednesday, Sept. 4

7:30 a.m. – 8:30 a.m.

**BREAKFAST**

8:45 a.m. – 9:00 a.m.

**WELCOME SESSION**

**Linda Sullivan, Co-Founder and Executive Director, Metrics Champion Consortium**

9:00 a.m. – 10:00 a.m.

**Secrets to Implementing Successful Metric Programs**

- ▣ Deciding what to measure — tools and metric maturity model (metrics, systems, people, process)
- ▣ Establishing data requirements
- ▣ Aggregating reliable data in a timely manner — make or buy?
- ▣ Designing metric reports that are easy to understand and provide context
- ▣ Using metrics to identify areas of concern and conducting root cause analysis to understand opportunities to improve performance

**Keith Dorricott, Contractor for the Metrics Champion Consortium; Director, Dorricott Metrics & Process Improvement Limited**

**Michael Fitzpatrick, Associate Director, Sarepta**

**Ravin Warnakulasuriya, Senior Director, Vertex Pharmaceuticals**

**Nancy Dynes, Metrics Consultant, Eli Lilly and Company**

10:00 a.m. – 10:15 a.m.

**BREAK**

10:15 a.m. – 11:00 a.m.

**Secrets to Implementing Successful Metric Programs (continued)**

11:00 a.m. – 12:00 p.m.

**KEYNOTE SESSION****Tracking the Patient Engagement Movement and its Impact on Clinical Research Execution**

**Kenneth Getz, Director of Sponsored Programs and Associate Professor, Tufts University; Founder and Board Chair, CISCRP**

12:00 p.m. – 1:00 p.m.

**LUNCH**

## VENDOR OVERSIGHT

1:00 p.m. – 1:45 p.m.

### WELCOME SESSION

- What is vendor oversight?
- What do the regulatory authorities expect: stories from the trenches of regulatory authority inspections?
- Normalizing terminology: vendor oversight vs vendor management — are they the same thing?

**Liz Wool, President, Wool Consulting Group, LLC**

1:45 p.m. – 2:15 p.m.

### PRESENTATION

#### Managing the Business of Inefficient Oversight: How Heavy (or Light) is Your Touch When it Comes to Overseeing Vendors?

Vendor oversight is a hot topic these days as companies try to find implementation strategies to satisfy the ICH E6 (R2) vendor oversight guidelines. From formalized vendor risk-based selection criteria to oversight SOPs to complex vendor management plans, Sponsors are interpreting the guidelines in different ways to avoid negative inspection findings at all costs. From all vantages, taking a risk-based approach to vendor oversight makes good sense and should theoretically be more efficient ... but is it?

- Do larger companies (with more resources) oversee their vendors less efficiently than smaller companies?
- Are sponsor resources redoing some of the activities that are sourced to their vendors?
- How many internal resources are dedicated to vendor oversight activities? In what function do these resources reside?
- Are centralized vendor oversight functions common practice?

During this session, the speaker will describe current industry practices on the complexities and implementation strategies through interpretation of a detailed survey specific to vendor oversight requirements. The results of this survey will be discussed at this session to spur additional conversation on current practices. In other words, this is vendor oversight: according to you.

**Todd Johnson, Principal Consultant, Halloran Consulting Group, Inc.**

**Margaret Sabe, Principal Consultant, Halloran Consulting Group, Inc.**

## RISK-BASED QUALITY MANAGEMENT

1:00 p.m. – 1:30 p.m.

### WELCOME SESSION

- What challenges are organizations facing when implementing risk-based quality management programs?
- What does the term risk-based monitoring mean? Does it mean risk-based site monitoring or risk-based monitoring at a program/study level?
- How do you determine quality tolerance limits (QTLs)?
- How are organizations implementing centralized monitoring?

**Keith Dorricott, Contractor for the Metrics Champion Consortium; Director, Dorricott Metrics & Process Improvement Limited**

1:30 p.m. – 2:30 p.m.

### PANEL SESSION

#### Risk Management Emerging Practices and the Impact of ICH E6(R2) Updates

- Risk-based quality management in an outsourced model
- Risk libraries — benefits and challenges
- Practicalities of risk assessment — critical process, critical data, critical thinking

**Sandra (SAM) Sather, MS, BSN, CCRA, CCRC  
Vice President, Clinical Pathways, LLC**

**Steve Young, Chief Operations Officer, CluePoints**

**Dr. Oleg Shevaldyshev, Associate Director Quality Assurance, PRA Health Sciences**

**Kevin Douglass, Associate Director, DSI**

**VENDOR OVERSIGHT**

2:15 p.m. – 3:00 p.m.

**PANEL SESSION****Vendor Oversight Approaches and the Keys to Developing “Healthy” Sponsor/Vendor Engagements and Teams**

- Approaches to vendor oversight/vendor management in small, medium and large organizations with a focus on quality and performance
- Developing a partnership with vendors: what are the key attributes of the vendor staff and sponsor staff for ‘healthy’ engagements and teams

**Mary Brantner, Senior Director, Mallinckrodt Pharmaceuticals**

**Maria Makarovskaya, Senior Director, Tesaro, Inc. a GSK Company**

**Aaron Nolan, Consultant, Eli Lilly and Company**

3:00 p.m. – 3:30 p.m.

**BREAK**

3:30 p.m. – 4:15 p.m.

**CASE STUDY****An Evolving Approach to CRO Oversight — Challenges, Lessons and Takeaways**

- A sponsor describes its journey with oversight via metrics — going from theory to practice
- Challenges including cultural and change management aspects are presented
- Learn how to focus your oversight metrics on the vital few and some potential pitfalls in implementation

**Jehan Poco, Manager, DSI**

**David Anderson, Manager, DSI**

4:15 p.m. – 5:30 p.m.

**SMALL GROUP EXERCISE****Vendor Oversight Case Example**

Instructions:

- Review the case study
- Identify the vendors in the case study
- Identify vendors requiring oversight
- List 3 things for each vendor that requires oversight

**RISK-BASED QUALITY MANAGEMENT**

2:30 p.m. – 3:00 p.m.

**PRESENTATION****Normalization of Key Risk Indicators and Quality Tolerance Limits for Risk Detection**

**Steve Young, Chief Operations Officer, CluePoints**

3:30 p.m. – 4:15 p.m.

**PANEL SESSION****Risk-Based Site Monitoring Emerging Practices**

- How has implementation of risk-based quality management helped risk-based site monitoring?
- What risk-based site monitoring models are being implemented?

**Duncan Hall, CEO & Founder, Triumph Research Intelligence, Ltd.**

**Arturo Morales, Chief Technology & Data Officer, WCG Analgesic Solutions**

4:15 p.m. – 5:30 p.m.

**BREAKOUT GROUP DISCUSSIONS****Measuring Centralized Monitoring and Site Monitoring**

**Keith Dorricott, Contractor for the Metrics Champion Consortium; Director, Dorricott Metrics & Process Improvement Limited**

**Risk-Based Site Monitoring and Risk-Based Quality Management — KRIs & QTLs**

**Steve Young, Chief Operations Officer, CluePoints**

**Risk Management for Small Sponsors**

**Sandra (SAM) Sather, MS, BSN, CCRA, CCRC Vice President, Clinical Pathways, LLC**

**Development and Use of a Risk Library**

**Kevin Douglass, Associate Director, DSI**

**Keeping the Risk Assessment Up to Date**

**Duncan Hall, CEO & Founder, Triumph Research Intelligence, Ltd.**

**DAY 2 AGENDA** — Thursday, Sept. 5

7:30 a.m. – 8:30 a.m.

**BREAKFAST & MCC DEMOS****VENDOR OVERSIGHT**

8:30 a.m. – 9:30 a.m.

**OPENING SESSION**

- Re-cap day 1
- Risk-based vendor management overview: critical vendors for successful clinical programs
- Vendor oversight — the need to understand the work being performed to effectively manage and measure performance
- What are the foundational metrics that can be applied for all vendors?

**Liz Wool, President, Wool Consulting Group, LLC**

9:30 a.m. – 10:30 a.m.

**PANEL SESSION****Utilizing Metrics to Manage Vendor Risk and Performance**

- Critical vendors, inherent risks and approaches to manage the risks and the utilization of metrics for performance management and clinical trial integrity
- Contract research organization (CRO) metrics — what metrics will give you a good idea of their risks, performance and clinical trial health?
- Vendor metrics — designing metrics for all stakeholders — functional department, study teams and quality/compliance

**Tom Littleton, Director, PPD****Jacob Ehrlich, JD, MPH, Owner & Principal Consultant, Pure Health Consulting****David Anderson, Manager, Process Excellence and Risk Management, Daiichi Sankyo****RISK-BASED QUALITY MANAGEMENT**

8:30 a.m. – 8:50 a.m.

**OPENING SESSION**

- Re-cap day 1
- Introduction to critical thinking skills

**Keith Dorricott, Contractor for the Metrics Champion Consortium; Director, Dorricott Metrics & Process Improvement Limited**

8:50 a.m. – 9:30 a.m.

**PRESENTATION****Risk-Based Quality Management/Centralized Monitoring — What Skills are Needed?**

- Learnings from implementation of risk-based site monitoring
- Importance of team participation for critical thinking

**Nechama Katan, Associate Director, Central Monitoring, Pfizer**

9:30 a.m. – 10:30 a.m.

**PANEL SESSION****The Future of Risk-Based Quality Management (RBQM) ... What will it look like in 5 years?**

- Implementation of RBQM in virtual trials
- Risk-based study execution (RBx): Beyond risk-based monitoring
- Electronic Clinical Outcome Assessments (eCOA) and Electronic Patient Reported Outcomes (ePRO): High volume, non-case report form (CRF) data and RBQM
- What's the role of artificial intelligence and machine learning in RBQM?

**Johann Proeve, Chief Scientific Officer, Cytegrity****Steve Young, Chief Operations Officer, CluePoints****Olgica Klindworth, Director, PPD****Nechama Katan, Associate Director, Central Monitoring, Pfizer**

10:30 a.m. – 11:00 a.m.

**BREAK**

**RISK-BASED QUALITY MANAGEMENT**

11:00 a.m. – 12:00 p.m.

**BREAKOUT GROUP DISCUSSIONS****Measuring Centralized Monitoring and Site Monitoring**

Keith Dorricott, Contractor for the Metrics Champion Consortium; Director, Dorricott Metrics & Process Improvement Limited

**What Skills are Needed by CRAs and Centralized Monitors with Risk-Based Site Monitoring?**

Sandra (SAM) Sather, MS, BSN, CCRA, CCRC  
Vice President, Clinical Pathways, LLC

**Applying Artificial Intelligence/Machine Learning to Risk-Based Quality Management**

Nechama Katan, Associate Director, Central Monitoring, Pfizer

**Coordinating the Roles of Sponsor and CRO in Risk-Based Quality Management**

Olgica Klindworth, Director, PPD

**Challenges of Gathering Information to Support Risk Evaluation**

Linda Sullivan, Co-Founder and Executive Director, Metrics Champion Consortium