

# CLINICAL TRIAL RISK AND PERFORMANCE MANAGEMENT SUMMIT

SEPT. 4-5, 2019  
THE LOEWS PHILADELPHIA  
PHILADELPHIA, PA

A METRICS CHAMPION CONSORTIUM EVENT

## Agenda

### Day 1

7:30 a.m. – 8:45 a.m.

**Breakfast**

8:45 a.m. – 9:00 a.m.

**Welcome Session**

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

9:00 a.m. – 10:00 a.m.

**Secrets to Implementing Successful Metric Programs  
(Part 1)**

- Deciding what to measure – tools and metric maturity model
- 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, MCC Ambassador

Michael Fitzpatrick, Associate Director, Sarepta

Ravin Warnakulasuriya, Senior Director, Vertex

10:00 a.m. – 10:15 a.m.

**Break**

10:15 a.m. – 11:00 a.m.

**Secrets to Implementing Successful Metric Programs  
(Part 2)**

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**

The event now splits into two tracks, vendor oversight and risk-based quality management. Please choose the track that will help you the most.

## VENDOR OVERSIGHT

1:00 p.m. – 1:45 p.m. **WELCOME SESSION**

Liz Wool, MCC Ambassador

- 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?

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 standard operating procedures to complex vendor management plans, sponsors are interpreting the guidelines in different ways to avoid negative inspection findings at all cost. From all vantages, taking a risk-based approach to vendor oversight makes good sense and should theoretically be more efficient.

- 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.

**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, Head Global Development Operations Process, Mallinckrodt Pharmaceuticals

**3:00 p.m. – 3:15 p.m.**

**Break**

**3:15 p.m. – 4:00 p.m.**

#### **An evolving approach to CRO Oversight – Challenges, Learnings and Takeaways**

- A sponsor describes their 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, Process Excellence and Risk Management, Daiichi Sankyo Inc (confirmed)

David Anderson, Manager, Process Excellence and Risk Management, Daiichi Sankyo Inc (confirmed)

**4:30 p.m. – 5:30 p.m.**

### **SMALL GROUP EXERCISE**

**Vendor oversight case example**

**1:00 p.m. – 1:30 p.m.**

**WELCOME SESSION**

Keith Dorricott, MCC Ambassador

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?
- How are organizations implementing centralized monitoring?

**1:30 p.m. – 2:30 p.m.**

**PANEL SESSION**

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

- Current risk assessment practices
- Challenges with risk tools released prior to ICH E6(R2)
- Realigning methodologies to support review of critical data and critical processes
- Quality tolerance limits
- Risk-based quality management in an out-sourced model

SAM Sather, Vice President, Clinical Pathways, LLC.

Steve Young, Chief Operations Officer, CluePoints

Oleg Shevaldyshev, Associate Director, Quality Assurance, PRA Health Sciences

Kevin Douglass, Associate Director, Process Excellence and Risk Management, Daiichi Sankyo, Inc.

**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

**3:00 p.m. – 3:15 p.m.**

**Break**

**3:15 p.m. – 3:45 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?

Arturo Morales, Chief Technology & Data Officer, Analgesic Solutions

Duncan Hall, CEO and Founder, Triumph Research Intelligence Ltd.

**4:30 p.m. – 5:30 p.m.**

### **BREAKOUT GROUP DISCUSSIONS**

- Measuring Centralized Monitoring and Site Monitoring – Facilitator: Keith Dorricott
- Risk-based site monitoring Risk-based Quality Management - KRIs & QTLs - Facilitator: Steve Young
- Risk Management for Small Sponsors- Facilitator: SAM Sather
- Development and use of a Risk Library - Kevin Douglass
- Keeping the Risk Assessment up to date – Duncan Hall

**5:30 p.m. – 6:30 p.m.**

**Networking Reception**

**6:30 p.m. – 8:30 p.m.**

**Member-Only Dinner**

## **Day 2**

**7:30 a.m. – 8:30 a.m.**

**Breakfast and Metrics Champion Consortium Demos**

The event starts the day with our two tracks, vendor oversight and risk-based quality management. Please choose the track that will help you the most.

## **VENDOR OVERSIGHT**

**8:30 a.m. – 9:30 a.m.**

### **OPENING SESSION**

Liz Wool, MCC Ambassador

- Recap 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?

**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 organizations (CRO) metrics – What metrics will give me 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, Performance Measures, PPD

**10:30 a.m. – 11:00 a.m.**

**Break**

**11:00 a.m. – 12:00 p.m.**

## **SMALL GROUP EXERCISE**

### **Vendor oversight case example (cont.)**

- Use your table information and results from the day 1 activity
- Identify metrics for each of these categories:
  - Timeliness
  - Cycle Time
  - Quality
  - Relationship

**12:00 p.m. – 1:00 p.m.**

**Lunch**

## **RISK-BASED QUALITY MANAGEMENT**

**8:30 a.m. – 8:50 a.m.**

## **OPENING SESSION**

Keith Dorricott, MCC Ambassador

- Recap day 1
- Introduction to critical thinking skills

**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, Pfizer

**9:30 a.m. – 10:30 a.m.**

## **PANEL SESSION**

### **The Future of Risk-based Quality Management... What Will it Look Like in 5 Years?**

- How do you implement risk-based quality management in virtual trials?
- How do you implement risk-based quality management when you have large amounts of electronic clinical outcome assessment data?

Johann Proeve, Chief Scientific Officer, Cyntegrity

Steve Young, Chief Operations Officer, CluePoints

Olgica Klindworth, Director Data Analytics, PPD

Nechama Katan, Associate Director, Central Monitoring, Pfizer

**10:30 a.m. – 11:00 a.m.**

## **Break**

**11:00 a.m. – 12:00 p.m.**

## **BREAKOUT GROUP DISCUSSIONS**

- Measuring Centralized Monitoring and Site Monitoring – Facilitator: Keith Dorricott
- What skills are needed by CRAs and Centralized Monitors with Risk-based Site Monitoring? - SAM Sather
- Applying Artificial Intelligence / Machine Learning to Risk-Based Quality Management – Nechama Katan
- Co-ordinating the roles of sponsor and CRO in Risk-Based Quality Management - Olgica Klindworth
- Challenges of gathering information to support risk evaluation - Linda Sullivan

**12:00 p.m. – 1:00 p.m.**

## **Lunch**

We are all back together for the group exercises.

**1:00 p.m. – 2:30 p.m.**

## **INTERACTIVE SMALL GROUP EXERCISE**

## **Follow the Process and Data Trail – Moving from Data Reports to Action Plans**

In this group exercise, participants will be separated into teams competing to uncover the root cause(s) of issues described in a case study. Each team will be provided with a case study packet that includes a description of the organization and outsourcing vendors, protocol synopsis, data reports, questions to explore and a worksheet to record the discussion. Teams may ask facilitators for additional information as the need arises.

### **Exercise Wrapup**

Teams will compare results, how they worked through the analysis and reflect on lessons learned.

**2:30 p.m. – 3:00 p.m.**

**Summit Conclusion**