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# CLINICAL TRIAL RISK AND PERFORMANCE MANAGEMENT SUMMIT

NOV. 14-15, 2018  
THE WESTIN PRINCETON AT  
FORRESTAL VILLAGE  
PRINCETON, NJ

A METRICS CHAMPION CONSORTIUM/CENTERWATCH EVENT

## AGENDA

### DAY 1

**8:15 a.m. – 8:30 a.m.** Welcome

**Linda Sullivan**, Executive Director, Metrics Champion Consortium

**8:30 a.m. – 9:30 a.m.** **Overview of the Drug Development Landscape and the Evolving Role of Standardized Metrics in Monitoring, Informing and Predicting Performance**

- Drug development operating conditions and challenges
- Macro-level trends driving the need for more consensus-defined metrics
- Mapping the adoption of standardized metrics
- Projecting their future role and impact

**Ken Getz**, Associate Professor, Director of Sponsored Programs, Tufts CSDD and Founder and Board Chair, CISCRP

**9:30 a.m. – 10:15 a.m.** **ICHE6(R2) Section 5 - Using data to assess and manage risk, monitor safety and ensure data reliability**

- What should clinical research industry stakeholders keep in mind when implementing and managing risk-based quality management programs?
- Has the FDA conducted inspections of studies that used risk-based quality management approaches?
- How is the FDA using data to quantify risk to determine where to conduct site inspections?

FDA: **Dr. Jean Mulinde**, Senior Advisor, Division of Clinical Compliance Evaluation, CDER, FDA

**10:15 a.m. – 10:35 a.m.** Networking Break

**10:35 a.m. – 11:15 a.m. Defining what to measure to manage risk and improve clinical research quality and performance outcomes**

- What are metrics?
- What are organizations measuring today?
- How does ICH E6(R2) change the information that organizations need to design and manage studies?
- Is your organization measuring the most important things?
  - Do your metrics answer your high priority questions?
  - Do your metrics reward the behaviors you are seeking?
  - Do you measure time/cost/quality?

**Linda Sullivan**, Executive Director, Metrics Champion Consortium

**11:15 a.m. – 12:00 p.m. Next Gen Benchmarking in Biopharma**

Benchmarks have been a key component in effective R&D and clinical trial management across the Industry for decades. Initially benchmarks focused on speed were the primary target, but over the years the objectives expanded to a number of other areas: cost, success, quality, productivity, site performance, and contracting. These benchmarks have played an essential role in identifying opportunities for improvement.

Over the last few years, Industry has embraced the use of benchmarks in day to day operations as they have played an increasingly valuable role in project and trial planning and areas such as effective country and site selection.

Even more recently, the Industry has embraced more complex and analytical approaches to drive performance improvements. These techniques, built on machine learning, modeling, and advanced statistical approaches move beyond the general benchmarks to develop more sophisticated measures, models, and capabilities. Through our work we have seen these new approaches unearth a number of optimizations, specifically in country and site selection for clinical trials.

**Linda Martin**, President and Founder, KMR Group

**12:00 p.m. – 1:00 p.m. Lunch Break**

**1:00 p.m. – 2:00 p.m. Breakout Discussions**

1. ***How metrics influence behavior*** – What behaviors do your organization’s metrics program support/reward? Do they align with the behavior your organization wants to reward? (e.g. quality matters but you don’t track and reward quality, reward “firefighting” but not preventing problems)
2. ***How has implementing ICHE6R2 changed what you measure?***
3. ***Vendor oversight metrics – what to measure and how to use metrics?*** How does the sourcing model impact what you measure?

4. **Monitoring KRIs** – *Does your organization have a library of KRIs?* Do you use a core set of KRIs in all studies and add study-specific KRIs as needed?
5. **Staff development** – *Does your staff have the critical thinking skills needed to analyze your KRI and metric reports and take effective action?* How does your organization address the skills gap?
6. **Predictive Analytics** – are we collecting the right data to be able to get the output we are looking for?
7. **Small Sponsor Spotlight: The Unique Challenges of Managing Vendors When You are a Small Sponsor** – Do you use the same vendors as large sponsors? How do you ensure you work with experienced staff?

**2:00 p.m. – 2:15 p.m.      Sharing Ideas from Roundtable Discussions**

**2:15 p.m. – 3:10 p.m.      Risk Management Emerging Practices and the Impact of ICHE6(R2) Updates**

- Current risk assessment practices
- Challenges with risk tools released prior to ICHE6(R2)
- Realigning methodologies to support review of critical data and critical processes

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

Panelists:

**Duncan Hall**, CEO and Founder, Triumph Research Intelligence

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

**Johann Proeve**, Chief Scientific Officer, Cyntegrity

**Renee Ekeland**, Senior Quality Compliance Manager, CSL Behring

**3:10 p.m. – 3:30 p.m.      Networking Break**

**3:30 p.m. – 4:15 p.m.      Risk-Based Monitoring - Connecting Risk Assessment and Centralized Monitoring**

- Risk control and the D in LID (Likelihood, Impact, Detection)
- Key Risk Indicators and Quality Tolerance Limits: How is the industry approaching them?
- The role of Risk-Based Monitoring
- Using the data - critical thinking

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

Panelists:

**Kevin Douglass**, Associate Director, Process Excellence & Risk Management, DSI

**Nurcan Coskun**, Global Risk Based Monitoring Program and Technology Solutions Manager, Medtronic

**Rachel Oakley**, Director of Clinical Operations, Syneos

**Steve Young**, COO, CluePoints

**4:15 p.m. – 5:00 p.m. Predictive Analytics**

- What areas of clinical research are being explored (e.g. site selection, quality indicators, etc.)
- How are findings being applied and tested?

**Armelde Pitre**, Senior Director, Clinical Development Quality, Quality and Performance Risk Management, Pfizer

**5:00 p.m. – 5:10 p.m. Day 1 Wrap-Up**

**Linda Sullivan**, Executive Director, Metrics Champion Consortium

**5:10 p.m. – 6:30 p.m. Networking Reception**

**6:30 p.m. – 8:30 p.m. MCC Member Dinner**

**DAY 2**

**8:15 a.m. – 9:00 a.m. Breakfast**

**9:00 a.m. – 9:10 a.m. Welcome & Day 1 recap**

**Linda Sullivan**, Executive Director, Metrics Champion Consortium

**9:10 a.m. – 10:10 a.m. Does your staff have the critical thinking skills to evaluate risk, analyze KRI and metric reports and take appropriate action?**

- Is there a skills gap?
- What are “critical thinking skills”?
- How do you move away from the “check the box” mentality?

Moderator: **Linda Sullivan**, Executive Director, Metrics Champion Consortium

Panelists:

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

**Diane Thornton Chandler**, Principal Centralized Clinical Research  
Specialist, Medtronic

**Sam Sather**, Vice President and Co-founder, Clinical Pathways

**Jehan Poco**, Manager, Process Excellence and Risk Management, Clinical  
Development Operations, DSI

**10:10 a.m. – 10:30 a.m.** Break

**10:30 a.m. – 11:30 a.m. Setting the Foundation for Effective Performance Management:**

Using Gilbert's Behavioral Engineering Model (BEM) in Clinical Research

**Sam Sather**, Vice President and Co-founder, Clinical Pathways

**11:30 a.m. – 12:15 p.m. Getting to the root of the problem – there must be a better way!**

- Challenges of addressing the analytics skills gap
- Pros and cons of traditional root cause analysis approaches
- Case Example – easy to learn, effective approach to

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

**12:15 p.m. – 1:15 p.m.** Lunch Break

**1:15 p.m. – 3:00 p.m. Interactive Group Exercise**

Case Example – 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 Wrap-up

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

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

**Sam Sather**, Vice President and Co-founder, Clinical Pathways

**Linda Sullivan**, Executive Director, Metrics Champion Consortium

**3:00 p.m. – 3:15 p.m.** Closing Remarks

**Linda Sullivan**, Executive Director, Metrics Champion Consortium