

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. **Defining what to measure to manage risk and improve clinical research quality and performance outcomes**

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**

- Are organizations successfully implementing risk-based quality management approaches?
- What challenges have organizations encountered using risk-based quality management?
- How are agencies using data to quantify risk to determine where to conduct inspections?
- What advice can you give to clinical research industry stakeholders about implementing and managing risk-based quality management programs?

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

MHRA: **Kathleen Meely**, Senior GCP Inspector (invited)

MHRA: **Gail Francis**, Expert GCP Inspector (invited)

European Medicines Agency: **Fergus Sweeney**, Head of Inspections, Human Medicines Pharmacovigilance and Committees (invited)

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. Collecting & Reporting Risk and Performance Data

- Identifying end-user needs/requirements
- Designing data reports so end-users can interpret results
- Aggregating in-house and CRO/vendor data
- Addressing the challenges of data quality (data governance and data stewardship)

Mike Fitzpatrick, Senior Manager, Performance Operations Capabilities, Biogen (invited)

Ravin Warnakulasuriya, Senior Director Clinical Development Execution, Vertex Pharmaceutical (invited)

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 Consultancy

Oleg Shevaldyshev, Associate Director, Quality Assurance, PRA Health

Johann Proeve, Chief Scientific Officer, Cyntegrity

Renee Eckland, Senior Quality Compliance Manager, CSL Behring (invited)

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

3:30 p.m. – 4:15 p.m. Connecting Risk Assessment, Detectability and Centralized Monitoring – Pull Up a Seat at the Table!

- 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 (invited)

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 (invited)

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