Day 1

Tuesday, Sept. 8, 2020

9:00 AM **Private time to view pre-recorded sessions and prep for live discussions**
9:00 AM – 10:00 AM EDT

10:00 AM **Opening comments**
10:00 AM – 10:15 AM EDT

Linda Sullivan, MBA
Executive Director
WCG MCC

10:15 AM **Community Discussion**
10:15 AM – 11:30 AM EDT

Bridging the Gaps between CAPA and RBQM
Does your organization connect the programs?
How does your organization track and stratify “issues”?

Linda Sullivan, MBA (Discussion Leader)
Executive Director
WCG MCC

Oleg Shevaldyshev (Discussion Leader)
Associate Director, Quality Assurance
PRA Health Sciences

Risk-based Auditing
How does your organization decide which vendors and/or investigate sites to audit?

Maryann Livolsi, MSN RN (Discussion Leader)
GCP Compliance Leader
Bill & Melinda Gates Medical Research Institute

Liz Wool, CCRA, CMT (Discussion Leader)
President
Wool Consulting Group Inc.

Virtual/Remote Trial Oversight
How do you oversee and monitor virtual trials?
What data do you need to collect and review?
What is the role of the "site" monitor?

Arturo Morales, PhD (Discussion Leader)
Vice President, Technology Solutions
WCG

RBQM Training – The Foundation for Successful RBQM Implementation
RBQM training surfaced to be one of the most critical areas frequently preventing companies from making the first step into the RBQM direction. This hurdle has already been discussed between Cyntegrity and Merz in the pre-recorded presentation. This community discussion session will highlight in more detail the training content, how to get started (big bang or step-by-step), whom to involve, which studies might be good candidate vs not so good candidates, retrospective analyses vs RBQM implementation in a brand-new or ongoing study, when to be strict and when to be more relaxed, and other, potentially necessary hand-holding processes required for a successful start into the RBQM world. This is also your opportunity to ask any question related to the training or the RBQM implementation steps.

Johann Proeve (Discussion Leader)
Chief Scientific Officer
Cyntegrity

Nico Wegener (Discussion Leader)
Senior Clinical Project Manager
Merz Pharmaceuticals

Quality by Design: Protocol and Operational Complexity
How are organization assessing protocol and operational complexity? How do we use the assessment information to drive change?

Alec Vardy (Discussion Leader)
Executive Director
Jazz Pharmaceuticals

Frank Berger (Discussion Leader)
Head of Analytics, Global Clinical Operations
Boehringer Ingelheim

10:15 AM **Working Groups**
10:15 AM – 11:30 AM EDT

Key Risk Indicators (KRI)
Develop a list of commonly used KRIs and their effectiveness

Kevin Douglass (Working Group Leader)
Associate Director-Process Excellence & Risk Management
DSI

Steve Young (Working Group Leader)
Chief Scientific Officer
CluePoints

Vendor Oversight
What are the most important questions about vendor performance that your organization seeks to answer? What do you measure to answer the questions?

Keith Dorricott (Working Group Leader)
Director
Dorricott Metrics & Processes Improvement Limited

11:30 AM **Break**
11:30 AM – 12:00 PM EDT

12:00 PM **Group leaders recap discussion and working group outcomes**
12:00 PM – 12:30 PM EDT

12:30 PM **Group Exercise – Data Analytics Team Exercise Part I**

12:30 PM – 1:45 PM EDT

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 till be provided with a case study packet that includes a description of a clinical trial, data reports, questions to explore and a worksheet to record the discussion

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

Keith Dorricott (Facilitator)
Director
Dorricott Metrics & Process Improvement Limited

Linda Sullivan, MBA (Facilitator)
Executive Director
WCG MCC

1:45 PM **Recap and Closing Comments**

1:45 PM – 2:00 PM EDT

Linda Sullivan, MBA
Executive Director
WCG MCC

2:00 PM **Private time to view pre-recorded sessions and prep for live discussions**

2:00 PM – 4:00 PM EDT

4:00 PM **Day 1 Adjourns**

Day 2

Wednesday, Sept. 9, 2020

9:00 AM **Private time to view pre-recorded sessions and prep for live discussions**

9:00 AM – 10:00 AM EDT

10:00 AM **Opening comments**

10:00 AM – 10:15 AM EDT

Linda Sullivan, MBA
Executive Director
WCG MCC

10:15 AM **KEYNOTE: A Regulatory Compliance Perspective on Improving Clinical Trial Quality, Protection of Trial Participants, and Data Integrity**

10:15 AM – 10:45 AM EDT

- What should clinical research industry stakeholders keep in mind when implementing quality-by-design and risk-based quality management programs?
- Has FDA seen a shift in inspectional findings that suggest good clinical practice compliance and data quality improving?
- How does CDER use submission data to quantify risk to determine where to conduct BIMO inspections?
- Impact of the COVID-19 pandemic?

Jean Mulinde, MD
Policy Advisor
Division of Clinical Compliance Evaluation
Office of Scientific Investigations, CDER, FDA

10:45 AM Community Discussion Groups

10:45 AM – 12:15 PM EDT

Centralized/Onsite Monitoring Process Oversight and Metrics
How well are the centralized and onsite monitoring processes working? What does your organization measure?

Vera Pomerantseva (Discussion Leader)
Sr. Central Monitoring Lead
Brisol-Myers Squibb

Rachel Oakley (Discussion Leader)
VP RBQM Services
Triumph Research Intelligence

Vendor Oversight
How do you assess partnership quality?

Maria Makarovskaya, MA (Discussion Leader)
Global Strategic Sourcing, Clinical Category Management Lead
Corbus Pharmaceuticals

Monitoring Data Quality
How has the COVID pandemic changed how your organization monitors data quality?

10:45 AM Working Groups

10:45 AM – 12:15 PM EDT

Quality Tolerance Limit (QTL) Parameters
Develop list of commonly used QTLs

Leslie Sam (Working Group Leader)
Principal Consultant
Wool Consulting Group

Keith Dorricott (Working Group Leader)
Director
Dorricott Metrics & Process Improvement Limited

IT System Selection – How to Define and Estimate System Benefits before Selection.
Defining the benefits of a new system are critical for:

- Making the case to senior leadership
- Understanding what functionality truly drives the system's value and
- Determining how much the organization can really afford to invest in the new system

Yet, defining benefits is very challenging. As a result, many system selections do not have a clear benefit statement. During this work group session, participants will each develop a set of benefits and value estimates and share with each other to get support and help.

Gary Tyson (Working Group Leader)
Partner
Pharma Initiatives

Risk-Based Quality Management Conversations in the Field
In this working group we will focus on a break-out session where concepts can be applied to real work problems. Bring your study team conflicts to the discussion and work collaboratively to develop well thought out resolution strategies. With this exercise you will learn to write, mitigate and action signals like a champion at your next study team meeting!

Nechema Katan (Working Group Leader)
Director, Data Science Lead
Pfizer

Christine Panetti
Sr. Associate Central Monitor Risk-Based Monitoring
Pfizer

Jennifer Campbell
Clinical Data Analyst
CluePoints

12:15 PM **Break**
12:15 PM – 12:45 PM EDT

12:45 PM **Group leaders recap discussion and working group outcomes**
12:45 PM – 1:15 PM EDT

1:15 PM **Group Exercise – Data Analytics Team Exercise Part 2**
1:15 PM – 2:15 PM EDT

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 (Facilitator)
Director
Dorricott Metrics & Process Improvement Limited

Linda Sullivan, MBA (Facilitator)
Executive Director
WCG MCC

2:15 PM **Recap and Closing Comments**
2:15 PM – 2:30 PM EDT

Linda Sullivan, MBA
Executive Director
WCG MCC

2:30 PM **Private time to view pre-recorded sessions and prep for live discussions**
2:30 PM – 4:00 PM EDT

4:00 PM **Day 2 Adjourns**

Day 3

Thursday, Sept. 10, 2020

9:00 AM **Private time to view pre-recorded sessions and prep for live discussions**

9:00 AM – 10:00 AM EDT

10:00 AM **Opening comments**

10:00 AM – 10:15 AM EDT

Linda Sullivan, MBA
Executive Director
WCG MCC

10:15 AM **Community Discussion Groups**

10:15 AM – 11:45 AM EDT

The Risk-Based Monitoring Training Gap
Discuss ways to asses and address training gaps

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

Artificial Intelligence & Machine Learning
People, Process, Tools – How and Why to Upskill Your SMEs

- What AI/ML applications is your organization using to support/improve in clinical trial operations?
- How do you transform current SMEs into people who can leverage and/or design data science solutions?

Nechama Katan (Discussion Leader)
Director-Data Science Lead
Pfizer

Sagar Anisingaraju (Discussion Leader)
Chief Strategy Officer
Saama Technologies

False positives and False negatives in Risk Detection; Using them to find what's true

- Current challenges in statistical quality oversight
- Balancing false results as part of signal detection
- Understanding false positives and false negatives in risk detection
- Minimizing the occurrence of false results

Jonathan Rowe, PhD (Discussion Leader)
Associate Principal
ZS Associates

Steve Young (Discussion Leader)
Chief Scientific Officer
CluePoints

Transformation Management: Effective Strategy & Successful Adoption
This session describes methods and solutions for navigating transformational change. The audience will identify the potential risks associated organizational change and will discuss proven steps for effective transformation management.

Erika Stevens, MA (Discussion Leader)
Chief Operating Officer
Wool Consulting Group, Inc.

10:15 AM **Working Groups**
10:15 AM – 11:45 AM EDT

Risk Re-Assessment
Develop a list of events & milestones that trigger re-assessment during conduct

Gary Tyson (Working Group Leader)
Partner
Pharma Initiatives

11:45 AM **Break**
11:45 AM – 12:30 PM EDT

12:30 PM **Group leaders recap discussion and working group outcomes**
12:30 PM – 1:0 PM EDT

1:O0 PM **vSummit Concludes**