MARCH 22-23, 2018 | WYNDHAM PHILADELPHIA HISTORIC DISTRICT | PHILADELPHIA, PA

CENTRAL MONITORING SUMMIT

WHAT HAVE WE LEARNED AND WHAT'S NEXT?

Determine the process improvements that must be achieved after the implementation of RBM, allowing problems to be identified earlier in a study

CONFERENCE CO-CHAIRS

Lisa Berdan
Director Global Megatrials
DUKE CLINICAL RESEARCH INSTITUTE

Kimberly Nessel
Director, Clinical Scientist CVM
JANSSEN R&D

FEATURED SPEAKERS

David Bocobo
Senior Central Monitor — Risk-Based Monitoring
BRISTOL-MYERS SQUIBB

Sina Djali
Senior Director
THE JANSSEN PHARMACEUTICAL COMPANIES OF JOHNSON & JOHNSON

Oksana Gecha
Head of Central Monitoring Global Data Strategies and Solutions (GDSS)
BRISTOL-MYERS SQUIBB

Anne M. Smith
Consultant, Central Monitoring
ELI LILLY AND COMPANY

Elizabeth Robinson, RN, MSHS
Executive Director, Clinical Compliance and Operations
HORIZON PHARMA

Dr. Jaylaxmi Nalawade
Senior Manager — Drug Safety and Risk Management
LUPIN LIMITED

ROUNDTABLE DISCUSSION

What you need to know about the ICH GCP E6 (R2) and what it means for monitoring clinical trials.

SPECIAL FOCUS

- Discuss Case Studies and Practical Solutions Across Pharma on the Successful Implementation of Centralized Monitoring
- Adopt Change Management and Infrastructure Changes Needed in Adoption of Central and Remote Monitoring Practices
- Fine-Tune Responsibilities or Job Description of the Central Monitor
- Use Predictive Analysis for a Central CRA or Study Manager to Understand the Trends in Clinical Data and to See Critical Development Earlier

DEAR COLLEAGUE,

Risk-Based Monitoring (RBM) is no longer a new and innovative approach to monitoring in clinical trials: Chances are your organization has either dabbled in RBM or you've jumped in completely. The establishment of a central monitoring function is paramount to the success of an RBM strategy for clinical trials. What comes after your RBM process is established? Method improvement! At ExL Events' **Central Monitoring Summit**, our knowledgeable speaking faculty will share what has been found as part of their surveillance and the impact of central monitoring on the quality of research. Speakers will discuss their vision of the future of central monitoring and how it will be used in RWE and other types of pragmatic trials.

At the **Central Monitoring Summit** this March 22-23, heavy hitters from the industry will assemble to share strategies and crucial information for the successful adoption and implementation of central monitoring. Critical lessons will include:

- How the continued digitization of clinical research data will enable further expansion of off-site and central monitoring activities
- Learn what comes after years of RBM and how are companies are applying lessons learned
- Gain clarity on global regulatory expectations for risk-based quality focused on monitoring in clinical trials
- Managing the challenges that come with the implementation of new processes and innovative technology
- Discuss why best practices dictate using centralized monitoring to reduce the risk of misused resources and data

WHO SHOULD ATTEND

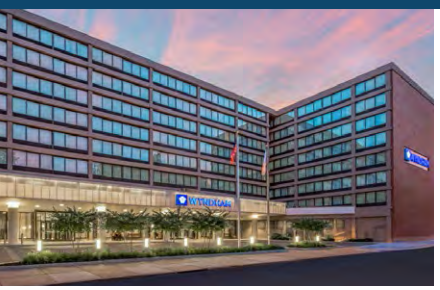
This conference is designed for representatives from pharmaceutical, medical device and biotechnology companies with responsibilities in the following areas:

- Monitoring
- Medical Review
- Clinical Data/Trial Management
- Trial Innovation/Design
- Quality Management
- Clinical Quality
- Clinical Research Associates (CRAs)
- Drug Safety
- Risk-Based Monitoring
- Surveillance

This conference is also of interest to:

- CRM/Data Management Software Vendors
- CROs
- Risk Consultants
- Risk-Based Monitoring Vendors
- Electronic Data Capture
- Clinical Analytics

VENUE | WYNDHAM PHILADELPHIA HISTORIC DISTRICT
400 ARCH ST., PHILADELPHIA, PA 19106



To make reservations, please call 1-877-999-3223 and request the negotiated rate for **ExL's March Meetings**. The group rate is available until **February 28, 2018**. Please book your room early, as rooms available at this rate are limited.

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8:00 REGISTRATION AND CONTINENTAL BREAKFAST

9:00 CO-CHAIRS' OPENING REMARKS

Lisa Berdan, *Director, Global Megatrials,* **DUKE CLINICAL RESEARCH INSTITUTE**

Kimberly Nessel, *Director, Clinical Scientist CVM,* **JANSSEN R&D**

ROUNDTABLE DISCUSSION

9:15 MANAGE STRATEGIES FOR ADOPTION AND IMPLEMENTATION OF ICH E6 (R2) AND EXPLORE HOW IT AFFECTS CENTRAL MONITORING

- Interpret the updated ICH E6 (R2) Guidelines
- Discover why RBM methodology requires Central Statistical Monitoring (CSM) to fulfill regulatory requirements and improve both quality and resource/cost efficiencies
- Use technology to minimize risk and issues and comply with guidelines

Moderator:
Lisa Berdan, *Director Global Megatrials,* **DUKE CLINICAL RESEARCH INSTITUTE**

10:15 STRATEGIZE FOR THE SUCCESSFUL ADOPTION AND IMPLEMENTATION OF CENTRAL MONITORING

- Embed a new CMN capability within an existing organization
- Use new and innovative technology, specifically the Centralized Statistical Analytics (CSA) software, in parallel with the creation of new processes
- Launch effective execution of a change management framework to help to successfully embed the CMN function within an organization
- Manage the challenges of the implementation process both internal and external to BMS

Oksana Gecha, *Head of Central Monitoring Global Data Strategies and Solutions (GDSS)*, **BRISTOL-MYERS SQUIBB**

David Bocobo, *Senior Central Monitor — Risk-Based Monitoring*, **BRISTOL-MYERS SQUIBB**

11:00 NETWORKING BREAK

11:30 ROLE OF MEDICAL REVIEW AS A COMPONENT OF CENTRAL MONITORING — JANSSEN CLINICAL TEAM APPROACH

- Develop the components of a Medical Monitoring Plan — what is important?
- Discuss the interdisciplinary approach to creating and reviewing medical review outputs
- Recognize the structure and get the most out of medical review meetings — planning, preparation, content, documentation and follow-up

Kimberly Nessel, *Director, Clinical Scientist CVM,* **JANSSEN R&D**

12:15 LUNCHEON

1:30 DISCOVER DRUG SAFETY ASSESSMENT IN CENTRAL MONITORING

- Adjust monitoring activities based on the issues and risks identified throughout the study
- Recognize KRIs that are measurable (quantifiable), comparable to assess the trends over the period of time and predictable to provide early warning signals
- Lead early and ongoing risk assessment — a focus on Critical Processes and Critical Data

Dr. Jaylaxmi Nalawade, *Senior Manager — Drug Safety and Risk Management*, **LUPIN LIMITED**

2:15 DISCOVER HOW TO IMPLEMENT RBM WITH ENDPOINT COLLECTION AS A FOCAL POINT OF CENTRALIZED MONITORING

- Implement TransCelerate's RBM approach
- Outline a centralized monitoring strategy with a strong focus on endpoint data completeness
- Design risk indicators for a proactive, targeted follow-up with sites

SPEAKER TBD

3:00 NETWORKING BREAK

3:30 DRILL DOWN ON DATA SETS TO IDENTIFYING INCONSISTENCIES BEFORE THEY IMPACT STUDY RESULTS

- Normalize observations by taking a holistic view of the site data
- Work on keeping Central Monitors (CMs) and Clinical Research Associates (CRAs) on track, only responding to triggers that require action

Sina Djali, *Head of Risk Management — Central Monitoring Integrated Data Analytics and Reporting Global Clinical Development Operations*, **JANSSEN R&D**

4:15 INTEGRATE QUALITY-BY-DESIGN INTO A CLINICAL TRIAL

- Obtain experienced clinical operators
- Achieve quality by addressing every single possible risk (any factor that poses a hazard to subject safety and/or data integrity and quality)
- Analyze how to become more targeted with KRIs when analyzing and measuring risk
- Avoid highlighting areas that don't need attention and failing to address those that should be a concern

SPEAKER TBD

5:00 END OF DAY ONE

8:00 REGISTRATION AND CONTINENTAL BREAKFAST

9:00 CO-CHAIRS' RECAP OF DAY ONE

Lisa Berdan, *Director Global Megatrials*, **Duke Clinical Research Institute**

Kimberly Nessel, *Director, Clinical Scientist CVM*, **JANSSEN R&D**

9:15 RESPOND TO THE SHIFTING ROLE OF A CRA, ACTIVELY SUPPORTING SITE STAFF TO TAKE GREATER OWNERSHIP OF PROCESS COMPLIANCE AND ACCURATE DATA REPORTING

- Increase remote or "off-site" monitoring to detect risk earlier and make more efficient use of "on-site" time
- Build strong relationships with sites even when "on-site" visits are decreased in frequency
- Understand how to be the central coordinator for site contacts across parties (sponsor, data management, medical monitor, vendors, etc.)

Elizabeth Robinson, *RN, MSHS, Executive Director, Clinical Compliance and Operations*, **HORIZON PHARMA**

10:00 NETWORKING BREAK

10:30 CASE STUDY: CENTRAL MONITORING: HOW OFTEN DO WE REALLY NEED TO GO ON-SITE?

- A tailored monitoring process has been put in place, now what is the reality of what is implemented by the site monitor?
- What interventions have/have not been implemented based on our experience? Are there country-level trends, regional trends, study level trends?
- How do we ensure we continue to see value from CM effort?

Anne M. Smith, *Consultant, Central Monitoring*, **ELI LILLY AND COMPANY**

11:15 IMPLEMENTING TRANSCELERATE'S RBM APPROACH — WHAT'S NEXT?

- Tying it all together — People, Process and Technology
- Evolving with advanced analytics
- Lessons learned from RBM sesign and adoption

Joanne Benedict, *Senior Advisor*, **ROCHE**

12:00 LUNCHEON

1:15 HEAR A SMALL COMPANY PERSPECTIVE ON THE USE OF CENTRALIZED MONITORING

- Learn why centralized monitoring for a low site trial could increase the risk of misused resources, data anomalies, and chasing operational metrics
- Ensure adherence to the study protocol and to look at data across patients from a centralized location
- Discuss how small companies using a targeted monitoring approach that is paired with centralized monitoring will benefit

Jennessa Martin, *Regulatory Affairs Coordinator*, **FIBROCELL SCIENCE**

2:00 NETWORKING BREAK

2:30 WORKING TOGETHER — SITE, SPONSOR AND CRO PERSPECTIVE

- Recognize how to best work with a CRO and site within a risk-based model
- Understand what the sponsor can do better to improve at the site level and if they are implementing RBM across all phases

Oksana Gecha, *Head of Central Monitoring Global Data Strategies and Solutions (GDSS)*, **BRISTOL-MYERS SQUIBB**

3:30 CONFERENCE CONCLUDES

EXL EVENTS' TESTIMONIALS

"While I'm 10+ years in the industry (18 months in Quality), I learned a lot! Great networking."
— Senior Clinical Quality Manager, **NOVARTIS**

"The discussions, presentations, interactions have provided a clear picture of common issues."
— VP Quality, **ALTASCIENCES**

"I was able to find weaknesses in my process that I will need to review."
— Director, CQA, **TREVENA**

"Members could share struggles, challenges, and ideas. It was also a good forum to build my network. As the conference went on, people seemed to share more lessons learned, shared learning, and tips/tricks. I liked this. It's more helpful to share challenges that are followed by solutions."
— Associate Director, Quality Systems, **VERTEX**

REGISTRATION
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web: http://pmaconference.com/
Mail: POB 2303 Falls Church Va 22042

Please make checks payable to: "PMA"

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EARLY BIRD PRICING
Register by Friday, February 2, 2018
$1,895

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Register After Friday, February 2, 2018
$2,095

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