



Utilize clinical performance metrics and innovative performance analytics to develop more efficient and cost-effective clinical trials while monitoring quality, compliance, and trial performance

15th CLINICAL PERFORMANCE METRICS & ANALYTICS SUMMIT

December 6–7, 2018
Sonesta Philadelphia Rittenhouse Square
Philadelphia, PA

FEATURED SPEAKERS



Chairperson
Tim Koch
Global Head of Clinical Analytics
NOVARTIS



Nancy Dynes
Metrics Consultant, Global Medical Quality
ELI LILLY AND COMPANY



Beth A. Soffer, B.A., M.A.
Sr. Director, QMS Analytics Lead, Clinical Development Quality, Global Product Development
PFIZER



Jim Kremidas
Executive Director
ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS
Ram Josyula



Wen-Yaw (Alex) Hsieh
Director, Quality Predictive Analytics
PFIZER



Ram Josyula
Master Black Belt Coach and AI Consultant
BRISTOL-MYERS SQUIBB

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COLLECT METRICS

- Define Optimal KPIs and Set Actionable Targeted Goals
- Be Proactive: Identify Objectives Before You Define KPIs



IMPROVE EFFICIENCY

- Improve Cycle Time From Draft Budget Received From Sponsor to Budget Finalize
- Improve Inefficient Reporting Systems and Produce Reliable, Relevant, Timely Data



LEVERAGE TECHNOLOGY

- Predictive Analysis: Calculate Risks and Allocate Resources
- Machine Learning and Artificial Intelligence: Improve Efficiency and Reliability



ESTABLISH TEAM DYNAMICS

- Monitor Communication Between All Components of Clinical Trails
- Improve Productivity With Clear and Measurable Standards



VENDOR PARTNERSHIPS

- Collaborative Strategies With CRO Partnerships for Optimal Success
- Utilize Performance Metrics to Track Partnership Performance

SPECIAL FOCUS

15th CLINICAL PERFORMANCE METRICS & ANALYTICS SUMMIT



WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical and biotech companies, clinical research sites, and academic research organizations with responsibilities in the following areas:

- Metrics and Benchmarks
- Quality assurance
- Data Systems / Management / Analytics
- Clinical Operations / Research / Planning / Outsourcing / Trials
- R&D Operations
- Patient Centricity Performance Management
- Process Optimization
- Risk-Based / Centralized Monitoring
- Site Performance Management
- Clinical Development / Project Management
- Study Management
- Trial / Clinical Compliance
- Audit
- Process Improvement
- Operational Effectiveness / Capabilities
- Information Systems / Resource Services
- Performance Analytics / Management
- Lean Six Sigma

Dear Colleague,

To ensure processes are on track, it is important to measure the performance of your organization, products, and especially, your clinical trials. During these expensive and long undertaking, collecting clinical performance metrics can be the key to ensuring the improvement of clinical trial processes and to building better relationships between sponsors, sites, and vendors. The 15th Clinical Performance Metrics Summit will bring together sponsors, CROs, and sites to discuss the importance of collecting clinical trial performance metrics/key performance indicators and using analytics to improve your trials performance, collaboration, and real-time monitoring.

Currently, because of reliance on automated systems, critical indicators are being overlooked. While these management systems are helpful tools, it is important to understand what and how to effectively measure, monitor, and analyze data during a clinical trial.

This year's conference will teach attendees to utilize clinical performance metrics and innovative analytics tools to develop more efficient and cost-effective clinical trials while monitoring safety, compliance, and trial performance.

Some of our featured sessions will address:

- The proactive collection of appropriate clinical metrics and how they can be used to time, quality, and efficiency from a sponsor, site, and vendor perspective
- New tools and methodologies to boost performance metric analytics and quality
- Innovative techniques that lead to proactive and comprehensive strategies for monitoring sites and decreasing risks
- Developing clear, measurable standards with focused KPIs for sponsors, sites, and vendors
- Increase preparedness for FDA inspections by understanding guidelines and learn strategies for compliance
- Collaborative strategies and effective communication with vendors to ensure partnerships are developed to their full potential

Join our esteemed faculty as they share invaluable insights, and return to work armed with the necessary tools and techniques you need to effectively measure clinical trials.

I look forward to seeing you in Philadelphia!

Sincerely,

Andrea Gianatiempo
Associate Conference Production Director

VENUE INFORMATION

Sonesta Philadelphia Rittenhouse Square
1800 Market St / Philadelphia, PA 19103

To make reservations, please call 1.800.SONESTA and request the negotiated rate for **ExL's 15th Clinical Metrics, 5th Rx-to-OTC, GDPR Update**. You may also make reservations online using the following weblink: <https://goo.gl/yhZTJL>. This group rate is available until **November 15, 2018**. Please book your room early, as rooms available at this rate are limited.

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8:00 *Registration and Continental Breakfast*

8:30 Chairperson's Opening Remarks

Tim Koch, *Global Head of Clinical Analytics, NOVARTIS*

9:15 **MEASURE METRICS THAT MATTER: UNDERSTAND WHAT TO MEASURE FOR OPTIMAL SUCCESS**

- Discuss the important metrics that are critical in helping in having a successful clinical trial
- Differentiate what metrics are vital and what metrics are not beneficial in measuring.
- Identify the who, what, where, when, why, and how of metrics and how to tailor it to each unique organizations values

10:00 *Networking Break*

10:30 **IMPROVE QUALITY OVERSIGHT THROUGH INTEGRATED TOOLS THAT PRODUCE RELIABLE, RELEVANT AND TIMELY DATA**

- Implement dashboards and tools that identify trends to focus resources to on managing and taking appropriate action early in a trial
- Identify important quality metrics critical to overseeing and identifying risky sites, studies, vendors, etc.
- Use quality metrics or other trends to identify sites for new trials
- Identify the who, what, where, when, why and how metrics are used to tailor tools to unique roles in the organization
- Gather user feedback and apply lessons learned to continuously improve correlations

Beth A. Soffer, B.A., M.A., *Sr. Director, QMS Analytics Lead, Clinical Development Quality, Global Product Development, PFIZER*

11:15 **MEASURE AND QUANTIFY IMPROVEMENT FOR GLOBAL TRIALS**

- The importance of developing a well-defined standard operating procedure (SOPs) for all aspect of the clinical trial
- Incorporate regulatory standards and guideline compliance using measures based off of SOPs
- Define expectations and continually measure the quality on a multi-site level to ensure efficient processes can be created and implemented

Nancy Dynes, *Metrics Consultant, Medicines Quality Organization, ELI LILLY & COMPANY*

12:00 *Networking Lunch*

1:00 **IMPLEMENT RISK MANAGEMENT FRAMEWORK TO DRIVE PROACTIVE PLANNING AND MITIGATION THROUGH THE LIFE CYCLE OF TRIAL**

- Capture and discuss action and trend risks and issues from the portfolio to trial, country, and site level
- Create a clear understanding of trial risks before deciding on a quality management track
- Understand how to utilize central monitoring and include key considerations for risk monitoring
- Leverage risk-based data to improve quality of clinical trials and understand how that data drives site selection

Snigdha Kodupuganti, *Associate Director, Data Sciences, Clinical Analytics, NOVARTIS*

2:00 **UTILIZE METRICS TO EFFECTIVELY MONITOR RISK AND COMPLIANCE**



Last year, the FDA began to require sponsors to proactively list risks and monitor accordingly. With the addendum ICH E6 R2 putting a larger emphasis on the responsibilities of CROs and sites to create a system for prioritizing risk-based approaches to how they monitor their clinical trials, sponsors and investigators are overlooking some key issues.

This panel will explore how all parties can stay on top of these overlooked issues and how metrics can be used to ensure that processes are not overlooked. Attendees will learn:

- How organizations are implementing a risk-based approach to oversight.
- Which key risk indicators (KRIs), performance metrics, and data points are being reviewed and who is responsible for reviewing them
- How trial design has evolved in a risk-based approach
- Lessons learned and best practices that can be shared around remote sites and even remote patient visits

Moderator:

Tim Koch, *Global Head of Clinical Analytics, NOVARTIS*

Panelists:

Todd Johnson, *Principal Consultant, HALLORAN CONSULTING GROUP*

Beth A. Soffer, B.A., M.A., *Sr. Director, QMS Analytics Lead, Clinical Development Quality, Global Product Development, PFIZER*

2:30 **Is Data Science the Treatment for Inefficiencies in Clinical Trial Operations?**
 Clinical trial recruitment statistics are very compelling. Nearly 50% of sites do not meet the recruitment timeline, and nearly 20% of sites do not recruit a single patient. To add to this, the complexity of trials and duration to complete these trials have increased by two-fold since 2010.

- Improve feasibility and site/investigator identification with analytics platforms that can help answer end to end questions
- Understand advance data science approaches to monitor risks and improve prediction of trial completion

Venkat Sethuraman, *Global Clinical Services Lead, ZS ASSOCIATES*

Sharma R D, *Business Process Manager, ZS ASSOCIATES*

3:15 **Cultivating a Clinical Operations Metrics Reporting Strategy and Transforming How Users Measure Performance and Process Improvement**

- Developing a metrics and analytics reporting strategy with the right metrics for the right business decisions
- Implementing an effective and impactful analytics reporting road map for the right user and the right level of information
- Lessons learned and best practices over the years

Judy Hwee, *Clinical Metrics and Reporting, AMGEN*

3:45 *Networking Break*

4:15 **INTERACTIVE SESSION: SELECTING AND LEVERAGING METRICS FOR EMERGING CLINICAL TRIAL STRATEGIES**



- Revolutionary approaches in designing, recruiting and conducting clinical trials
- Regulatory guidance that shapes deploying metrics for clinical trials
- Beyond KPIs: Are current metrics strategies leading to powerful data analytics?
- Opportunities and challenges in focusing and implementing new performance metrics
- Define, measure, analyze and deploy clinical metrics using lean sigma

Ram Josyula, *Master Black Belt Coach and AI Consultant, BRISTOL-MYERS SQUIBB*

5:45 Chairperson's Day One Closing Remarks

Tim Koch, *Global Head of Clinical Analytics, NOVARTIS*

6:00 Day One Concludes

"I am new to the Pharma field and I learned so much about the process in the past two days. Very good to hear different points of view from sponsor, CROs, and sites. Better than I expected. Every talk was very informative and practical."

—Quality Predictive Analytics Manager, PFIZER

"Great source for those who have to develop metrics from scratch – ideas to generate or what to look for."

—Clinical Quality Assurance Manager, TERUMO MEDICAL CORP

"The summit provided many starting points for me to investigate further as I learn more about the clinical world."

—QMS Oversight Monitoring Lead, JANSSEN

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8:30 Continental Breakfast

9:00 Chairperson's Recap of Day One

Tim Koch, *Global Head of Clinical Analytics*, **NOVARTIS**

9:15 **BEST PRACTICES FOR MANAGEMENT AND DETECTION OF OPERATIONAL AND CLINICAL RISK**

- Hear recent findings from Tufts CSDD that highlight areas of improvement in managing risk in clinical trials
- Learn approaches to risk scoring to assess performance and compliance across all levels of a portfolio of trials
- Gain insight into metrics and visualizations that identify outliers, and assist in collaboration to drive risk mitigation and improvement plans

Rick Morrison, *Founder and President*, **COMPREHEND SYSTEMS**

10:00 **DRIVE DECISIONS FOR CLINICAL DEVELOPMENT WITH IMPROVED ANALYTICS**

- Integrate analytics to improve R&D strategy and execution, with clear benefits to operational costs and long-term financial success
- Effective planning of analytics to ensure clinical data can be used to facilitate efficient improvements
- Embed analytics into the clinical development process to alleviate challenges and build partnerships with sites and vendors for better decisions

Angela Graves, *Development Operations: Senior Trial Logistics Manager*, **INCYTE PHARMACEUTICALS**

10:45 Networking Break

11:15 **UTILIZE MACHINE LEARNING AND ARTIFICIAL INTELLIGENCE TO UNDERSTAND THE QUALITY PERFORMANCE OF CLINICAL SITE**

- Understand how machine learning and artificial intelligence can aid in predicting risks of clinical sites
- Adapt the predictive model to better allocate resources and use its insight to determine high-risk factor and focus points
- Use both objective and subjective performance measures to determine the proactive actions to take when a high risk is predicted
- Case Study: Use machine learning and artificial intelligence to find data pathways and to determine high-risk factors and focus points

Alex (Wen-Yaw) Hsieh, *Director of Predictive Analytics*, **PFIZER**

12:00 Luncheon

1:00 **SITE IMPROVEMENT BY ENSURING STANDARDS AND PROPER KPI MEASUREMENTS**

- 
- How to excel in your trials by leveraging metrics used by sites to improve sponsor relations and internal operations
 - Gain a better understanding of which metrics sites evaluate internally to best run their operations
 - Learn how to improve sponsor relationships by proactively comparing site metrics to sponsor expectations
 - See the impact on site quality and speed based on personnel certification status

Moderator:

Tim Koch, *Global Head of Clinical Analytics and Innovation*, **NOVARTIS**

Panelists:

Jim Kremidas, *Executive Director*, **ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS**

Song Liu, M.D., Ph.D., *Sr. Director, Clinical Affairs*, **IMPERATIVE CARE**

Susan Johansson, *CCRA, Associate Director, Clinical Operations*, **PACIRA PHARMACEUTICALS**

Johanna Ledley, *Technical Research Assistant*, **BRIGHAM AND WOMEN'S HOSPITAL**

2:00 **FOCUS KPIS AND MONITOR CENTRALIZED GOALS WHEN LAUNCHING QUALITY IMPROVEMENT PROJECTS**

- Plan utilization of KPIs proactively to fulfill objectives to ensure effectiveness and better allocate timing.
- Measure the proper KPIs and how to avoid common errors in inefficient measurements
- Develop and launch quality improvement projects by using metrics to improve the process and sustain improvement

Linda Peterson, *Associate Director, Clinical Operations and Global Integration*, **INOVIO PHARMACEUTICALS**

2:45 Chairperson's Closing Remarks

Tim Koch, *Global Head of Clinical Analytics*, **NOVARTIS**

3:15 Conference Concludes

To Register, Click Here, or

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POB 2303
Falls Church VA 22042

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15th CLINICAL PERFORMANCE METRICS & ANALYTICS SUMMIT



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December 6-7, 2018

Sonesta Philadelphia Rittenhouse Square
Philadelphia, PA

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–Register by October 19, 2018	
STANDARD PRICING	\$2,095
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