13th CLINICAL PERFORMANCE METRICS SUMMIT

Ensure Trial Success and Enhance Study Operations Through the Application of Quality Performance Metrics

December 5-6, 2016 | Sheraton Philadelphia University City Hotel | Philadelphia, PA

TOP REASONS TO ATTEND:

• Enhance your understanding of clinical metrics and the data that drives them

• Master methodologies to improve performance metrics analytics and quality

• Focus on overcoming challenges to metrics optimization and improving site selection using metrics tools with industry leaders

• Discuss the new and existing guidances of the Food and Drug Administration and how performance metrics and benchmarking will be affected

• Discover the data sites are measuring and what can be done to support their efforts

NEW SESSIONS INCLUDE:

• Use Leading Indicators to Enhance Performance and Improve Quality in Clinical Trials

• Implement a Metrics System in Partnership with a CRO

• The Association of Clinical Research Professionals’ Efforts to Improve Clinical Quality Across the Industry

• PANEL DISCUSSION: Overcome Hurdles and Roadblocks to Implement a Performance Metrics System

• Find Tools and Data to Focus on Measuring with Meaning

• CASE STUDY: Pfizer’s Study Quality Risk Prediction Model

FEATURED SPEAKERS INCLUDE:

ALEXION PHARMACEUTICALS
Austin Allan
Senior Director R&D Quality Processes and Systems

ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS
Jim Kremidas
Executive Director

BRISTOL-MYERS SQUIBB
Ram Josyula
Lean Six Sigma Master Black Belt Coach

DREXEL UNIVERSITY
Michael Howley, PA-C, Ph.D.
Associate Clinical Professor, LeBow College of Business

ELI LILLY AND COMPANY
Nancy Dynes, MBA,
Metrics Consultant, Medicines Quality Organization

PFIZER
Jonathan Rowe, Ph.D., M.S., M.A.
Executive Director, Head of Clinical Development Quality Performance and Risk Management

“Excellent examples, engaging presentations. Really enjoyed the overall experience!”
—Senior Manager, Process Improvement, Developmental Sciences, BIOMARIN PHARMACEUTICALS
Who Should Attend

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

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

This event is also of interest to:

- CRM/Data Management Vendors
- Academic Research Organizations/Clinical Research Organizations
- Dashboard and Monitoring Organizations
- Institutional Review Boards
- Clinical Trial Management Vendors
- Regulatory Consultants

Dear Colleague,

Now more than ever — and specifically in drug development — all facets of your daily operations are measured for quality. Clinical trials are no exception, and metrics provide the basis for companies to improve the quality of their work; if it can be measured, it can be improved. To facilitate this conversation, ExL has ushered in an era of understanding with our advanced and innovative conference for sponsors, sites, CROs and service providers. Here all stakeholders discuss challenges and solutions that can impact their daily trials while providing real-world examples and take-home strategies.

ExL Events’ Clinical Performance Metrics Summit is an educational platform where more than 500 industry professionals have networked and collaborated on industry topics. This year, with collaboration and discussion around metrics optimization, clinical trial improvement and the usability of performance metrics, ExL will continue that trend with a program of new topics and methodologies.

The 13th Clinical Performance Metrics Summit is this year’s key event for leaders in the pharmaceutical and research industry to:

- Collaborate and network with other thought leaders on methodology and metrics optimization
- Develop new methodologies and a better understanding of metrics management and collection
- Use data collaboration to improve the industry’s ability to evolve and change clinical trial operations
- Navigate metrics system implementation while involving and considering trial stakeholders

I encourage you to attend the 13th Clinical Performance Metrics Summit. ExL Events has more than a decade of experience assisting clinical professionals improve their metrics systems, and I am confident summit delegates will discover new trends and perspectives. Over the course of two days, attendees will take part in an overview of stakeholders and the industry; engage in conversations to enhance the collection of metrics; find new methods to forecast, understand and analyze clinical trial success; and target challenges and strategize how to overcome them while implementing change. Join us to improve yourself and your company.

M. [Signature]

Venue

Sheraton Philadelphia University City Hotel
3549 Chestnut St.
Philadelphia, PA 19104

If you require overnight accommodations, please contact the hotel. ExL Events has reserved a block of rooms at a group rate. To make reservations, please call 1-888-627-7070 and request the group rate for ExL’s December Meetings. We encourage attendees to book their rooms by November 14, 2016. Please book your room early, as rooms available at this rate are limited.

*ExL Events is not affiliated with Exhibition Housing Management (EHM)/Exhibitors Housing Services (EHS) or any third-party booking agencies, housing bureaus, or travel and events companies. In the event that an outside party contacts you for any type of hotel or travel arrangements, please disregard these solicitations and kindly email us at info@exlevents.com. ExL has not authorized these companies to contact you and we do not verify the legitimacy of the services or rates offered. Please book your guest rooms through ExL’s reserved guest room block using the details provided.
11:00 Networking Break

11:30 Incorporate the Site Perspective to Improve Partnerships in Clinical Quality
› Discover the relationship between clinical research sites and performance metrics and how sites gather and analyze data
› Discuss the processes sites use to measure effectiveness and achieve continuous improvement
› Improve performance metrics by establishing partnerships and examining site operations
› Delve into the hurdles and problems sites overcome and the solutions they use to constantly improve quality and care
› Assess how to assist sites as they implement metrics systems

Jeff Kingsley, DO, MBA, CPI, Chief Executive Officer, IACT HEALTH

12:15 Luncheon

METRICS COLLECTION

1:15 Implementing a Sustainable, Cross-Functional Approach to Metrics in Drug Development
› Reduce fragmentation and eliminate silos in the definition and use of performance metrics
› Design and build a common foundation and platform as the single source of current and historical performance
› Define and implement governance processes and the role of metrics
› Develop and execute change management strategies to drive culture toward managing with metrics
› Enable the “Science of Operations” in drug development

Polina Kuznetsova-Nguyen, Business and Scientific Operations Manager, NOVARTIS

2:00 Find Tools and Data to Focus on Measuring with Meaning
› Understand the use and importance of metrics to create meaning
› Recognize that measures in the absence of action are meaningless — they are just numbers
› Discover the types of metrics that provide actionable insight into quality and overall performance management
› Apply the right tools to guide the appropriate audience

Austin Allan, Senior Director R&D Quality Processes and Systems, ALEXION PHARMACEUTICALS

2:45 Networking Break

3:15 Develop a Metrics Methodology to Ensure Clarity in Data Stories
› Identify methods to enhance your data set and expand the information that can be drawn from it
› Ensure data is relatable as an organization collects and collates information from clinical studies and projects
› Learn how an organization can account for anecdotal information and ensure the information and assumptions that contributed to the data points are reflected or accounted for

Beibhinn O’Donoghue, Principal Business Analyst, VERTEX

4:00 Use Leading Indicators to Enhance Performance and Improve Quality in Clinical Trials
› Evaluate the clinical trial industry’s quality problem and learn how to measure quality in a scientific way
› Challenge and analyze the traditional approaches to measuring quality as the root cause for failing to meet goals and stay under budget during a clinical trial
› Assess how leading indicator metrics can improve the quality of clinical trials and patient care and ensure trial success

Michael Houley, PA-C, Ph.D., Associate Clinical Professor, LeBow College of Business, DREXEL UNIVERSITY

4:45 Day One Concludes

“Very well organized and engaging! Great examples.”
—Senior Project Manager, TEVA PHARMACEUTICALS
AGENDA  DAY TWO — TUESDAY, DECEMBER 6

8:00  Continental Breakfast

8:30  Chairpersons’ Recap of Day One
   Ravin Uwarnakulasuriya, Senior Director, Clinical Development Execution, VERTEX
   Linda Sullivan, President and Co-Founder, METRICS CHAMPION CONSORTIUM

8:45  Use Past Data to Better Understand Future Quality in Clinical Trials
   › Learn the new techniques and methodologies of top companies that use past data to improve present and future clinical trials
   › Leverage data from past trials to define performance and process metrics
   › Reshape the methodology and scope of future trials based on performance metrics data analytics
   › Engage in conversation to understand what pertinent past data is available and how to use it effectively and efficiently in clinical trials
   Ram Josyula, Lean Six Sigma Master Black Belt Coach, BRISTOL-MYERS SQUIBB

9:30  Use Clinical Metrics to Better Plan for Changes in Trial Performance
   › Incorporate multiple data sources and types to provide an full view of trial performance
   › Review metrics for early detection of signals to determine necessary remedial actions to be taken
   › Decrease error and variability by improving processes based on root cause analyses
   Nancy Dynes, MBA, Metrics Consultant, Medicines Quality Organization, ELI LILLY AND COMPANY

10:15 Networking Break

10:45  CASE STUDY: Pfizer’s Study Quality Risk Prediction Model
   › Demonstrate the statistical model that allows clinical trial teams to understand the risk their protocol has regarding the likelihood of protocol deviations, protocol amendments and other significant quality events
   › Assess the relationship between proactive clinical trial quality risk management, risk identification and mitigation
   › Explore the current use of the model as part of the protocol approval process
   › Consider the importance of refreshing the model on a regular basis to account for advances in clinical trial design and execution as well as newly identified quality risks
   Jonathan Roue, Ph.D., M.S., M.A, Executive Director, Head of Clinical Development Quality Performance and Risk Management, PFIZER
   Alex (Wen-Yaw) Hsieh, Director, Quality Performance and Risk Management, PFIZER

11:30 The Association of Clinical Research Professionals’ Efforts to Improve Clinical Quality Across the Industry
   › Use rigorous scientific measurements of clinical trial performance to understand the perspectives of all stakeholders, including patients and sites
   › Identify data beyond standard operational KPIs, which can hinder root-cause analysis and solutions
   › Better understand and address factors driving trial execution and quality
   › Discuss the Association of Clinical Research Professionals’ focus on clinical trial excellence and the organization’s commitment to the development and use of tools and processes necessary to support valid and reliable performance measurement
   › Review the initial data generated by these efforts and discuss how that data can help all stakeholders improve clinical trials
   Jim Kremidas, Executive Director, ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS

12:15 Luncheon

CHANGE IMPLEMENTATION AND OVERCOMING CHALLENGES

1:15  CASE STUDY: The Implementation of a Clinical Data Analytics System for Outsourced Trials
   › Assess the rationale and reasoning for Jazz to utilize an internal clinical data analytics system, in addition to a CRO’s system
   › Explore the system’s implementation, conception, process and planning, preferred architecture, and data mapping
   › Learn how designing dashboards and metrics properly can provide transparency and sponsor oversight
   Sean Gharpurey, Executive Director, R&D Strategic Business Improvement, JAZZ PHARMACEUTICALS

2:00 Networking Break

2:30  Implement a Metrics System in Partnership with a CRO
   › Take advantage of the relationship and use it to enhance the metrics system
   › Investigate the implementation of the performance metrics system from conception to completion
   › Weigh the benefits of partnering with a CRO to implement the system
   › Work with cross-functional teams to develop workflows and hierarchies that organize and streamline clinical trials
   › Use the CRO to vet and test systems to cut costs and improve outcomes
   Mike Fitzpatrick, Manager, Performance Operational Capabilities, BIOGEN

3:15  PANEL DISCUSSION: Overcome Hurdles and Roadblocks to Implement a Risk-Based Monitoring System
   › Discover the process to choose the correct system and customize it to coordinate with business needs
   › Navigate the process of a successful risk-based monitoring implementation and what steps should be taken
   › Overcome kickback from stakeholders and others affected by the RBM implementation
   Investigators: Teresa Ancukiewicz, Senior Manager, CDM, BOSTON SCIENTIFIC
   Mike Fitzpatrick, Manager, Performance Operational Capabilities, BIOGEN
   Ram Josyula, Lean Six Sigma Master Black Belt Coach, BRISTOL-MYERS SQUIBB

Panelists:
   Taylor Uttley, Senior Clinical Project Manager, VERTEX
   Moderator:
   Sean Gharpurey, Executive Director, R&D Strategic Business Improvement, JAZZ PHARMACEUTICALS

4:00  Chairpersons’ Closing Remarks
   Ravin Uwarnakulasuriya, Senior Director, Clinical Development Execution, VERTEX
   Linda Sullivan, President and Co-Founder, METRICS CHAMPION CONSORTIUM

4:15 Conference Concludes
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Registration Fees for Attending ExL’s 13th Clinical Performance Metrics Summit:

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<th>Early Bird Pricing</th>
<th>Standard Rate Pricing</th>
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<td><strong>EBP</strong></td>
<td>Register by October 21, 2016</td>
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<td><strong>SRP</strong></td>
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GROUP DISCOUNT PROGRAM

Offers may not be combined. Early bird rates do not apply. To find out more on how you can take advantage of these group discounts, please contact our offices at (210) 871-0474.

**PER PERSON WHEN REGISTERING FOUR**

For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

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