Clinical Performance Metrics and Benchmarking Summit

Implement Effective Performance Metrics to Monitor Risk, Site Selection, and Quality of a Highly Functioning Clinical Trial

December 10 – 12, 2014  Loews Philadelphia Hotel | Philadelphia, PA

FEATURED FACULTY:

1. Uncover strategies to develop, implement, and utilize performance metrics in order to proactively measure and assess trial compliance
2. Identify site selection metrics to select the appropriate site, reduce costs, and shorten enrollment times
3. Discover ways to develop benchmarks that enhance the implementation of key performance indicators
4. Understand the impact that global quality performance metrics have on the industry
5. Utilize data acquired through predictive analytics to drive proactive action in Risk-Based Metrics

TO REGISTER CONTACT ADRIANA MURILLO | AMURILLO@EXLPHARMA.COM OR 917-258-5142
Dear Colleague,

ExL Pharma’s 11th Clinical Performance Metrics & Benchmarking Summit will bring together senior-level executives from pharmaceutical and biotechnology companies to examine case studies and solution-driven applications of clinical performance metrics. Our speaking faculty is comprised of thought leaders who understand the importance of running clinical trials that are efficient, to a high-quality standard, and on budget. This conference is dedicated to ensuring that the audience will leave with various methods being used across the industry to effectively track and measure clinical performance.

Incorporating the leading industry performance metrics into a company’s operational plan can reveal the best practices behind improving efficiency and decreasing costs. The 11th Clinical Performance Metrics & Benchmarking Summit, held December 10 - 12, 2014 in Philadelphia, PA will provide tools and solutions to drive proficiency and performance during clinical development.

Join us to gain key insight behind developing, using, and implementing performance metrics in order to proactively measure and assess trial compliance. Together, we will explore all this and more through an entire Workshop Day on Quality and Risk Metrics followed by two days filled with extensive educational sessions led by the industry’s top professionals.

We can’t wait to see you in December!

Sincerely,

Brendan Weiss
Conference Producer
ExL Pharma

Scott Grossman
Division Head, Conference Productions
ExL Pharma

WHO SHOULD ATTEND:
This conference is designed for professionals from pharmaceutical, biotech, and clinical research with responsibilities in the following areas:

- Metrics and Benchmarks
- Clinical Operations/Research/Planning/Outsourcing
- Study Management
- Clinical Development & Project Management
- Quality Assurance
- Data Management
- Trial Compliance
- Recruitment
- Process Improvement
- Operational Effectiveness
- Site Performance Management
- Information Systems/Resource Services
- Data Analytics

SPONSORSHIP AND EXHIBIT OPPORTUNITIES
Do you want to increase awareness of your organization’s thought leadership and solutions with the clinical operations audience? Take advantage of the opportunity to present an educational session, host a networking event, distribute promotional items, or exhibit. ExL works closely with you to customize a package that aligns with your strategic goals.

To learn more about these opportunities, contact Andrew Ferguson, Business Development Manager at 917-258-5150 or aferguson@exlpharma.com

“Great networking opportunity and knowledge sharing”
— Associate Director of Quality and Process Excellence, NOVARTIS

“Very informative and thought provoking. Enlightened me on upcoming expectations and helped me better understand the importance of learning how to interpret all of this”
— Senior CRA, RHO, Inc.

 Venue:

Loews Philadelphia Hotel
1200 Market Street
Philadelphia, PA 19107

If you require overnight accommodations, please contact the hotel to book your room. ExL Pharma has reserved a block of rooms at a discounted rate for conference participants. We encourage conference participants to make reservations by November 19, 2014. To make reservations guests can call 1-888-575-6397 and request the negotiated rate for “ExL’s December Meetings.”

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WORKSHOP DAY
Wednesday, December 10th, 2014

8:00  Registration and continental breakfast for Workshop A attendees

9:00  Workshop A
Uncover the Proactive Measurement of Clinical Trial Quality and Performance
Designed for the non-statistician, this workshop is designed for professionals who must use quality or performance data to manage clinical trials, perform risk-based monitoring, create dashboards, or lead Quality by Design (QbD) initiatives. This workshop will explore the processes behind choosing scientific (i.e. valid and reliable) performance measures. In addition, this workshop will discuss the top practices behind generating scientific measures of clinical trial quality that can be used to assess performance and guide quality investments. Attendees will leave with the ability to successfully complete the following tasks:

- Assess the validity and reliability of specific industry measurements
- Develop effective and efficient performance measures
- Identify the best possible strategies to manage clinical trial quality management

Michael Howley, PA-C, PhD, Associate Clinical Professor, LeBow College of Business, Drexel University

12:00  Workshop A concludes - Lunch for all Workshop A attendees

12:30  Registration for Workshop B attendees

1:00  Workshop B
Develop A Quality Metrics Roadmap
Demands from regulators to deliver ‘trials with quality’ has captured the need to ‘measure for quality’, and subsequently the development of ‘quality metrics’. Simply tracking protocol deviations does not cover all the critical quality factors related to bringing a product to market. In order to capture, measure, and report on quality metrics, the organization requires both a strategy and framework for quality management across the business enterprise. Utilizing a hands-on approach through collaboration, attendees will leave the workshop equipped to move forward with a quality metrics strategy and the ability to develop and deploy quality metrics for their organization. This workshop provides a review of the core foundation and framework needed to identify and report on quality metrics:

- Identification of the quality, data reliability, and report supporting regulatory authority submissions for approval
- Designing the tools to collect data for ‘quality metrics’
- Analyzing organization activities for quality metrics reporting

Liz Wool, President & CEO, QD-Quality and Training Solutions, Inc
Linda Sullivan, Chief Operating Officer, MCC
Joan B. Versaggi, BS, MBA, Principal, QPM Solutions, LLC

4:00  Workshop Day concludes

DAY TWO
Thursday, December 11th, 2014

8:00  Registration and continental breakfast for main conference attendees

8:45  Chairperson’s opening remarks
David Zuckerman, Co-Owner, MCC

9:00  Case Study: Drug Design and Implementation of RBM Metrics
Surfacing the relationship that an IRB has with Risk Based Metrics
Uncovering the FDA Regulations that an Institutional Review Board must operate under
Analyzing the ethical umbrellas placed over IRBs and clinical trial patients to create a quality assessment

Nancy Dynes, Global Medical Quality Metrics, Eli Lilly and Company

9:45  Apply Management Metrics to Derive Insights into Drug Development Operating and Practice Trends
Review recent Tufts CSDD results highlighting major drug development landscape trends
Present metrics from Tufts CSDD on protocol design practices and their impact on development performance and cost
Discuss Tufts CSDD metrics providing insights into maximizing investigative site operating practices

Ken Getz, Director, Sponsored Research Programs, Tufts, Chairman, CisCRP

11:00  Enable Strategic Site Selection and Benchmarking Through the Utilization of Metrics and Dashboards While Driving Organizational Change
Capturing and validating data via strategic sourcing and data stewardship
Reinforcing data adoption through organizational change management
Framing data for consumer convenience through the development of dashboards, reports and tool

Taylor Uttley, MS, Principal Clinical Business Analyst, Clinical Performance, Vertex Pharmaceuticals, Inc

11:45  Case Study: Understand Multi-Center, Global, Clinical Trial Site Activation
Enhancing methods behind understanding site activation cycle times for a multi-center clinical trial
Uncovering top practices for project management and analysis planning for site activation
Learning best strategies behind proactively summarizing the speed of first patient treatment

Jack Faricelli, MSc., Associate Director, Bristol-Myers Squibb
Brittany Grasela, Data Analyst, Bristol-Myers Squibb
Amanda Olar, MBA Intern, Tepper School of Business, Carnegie Mellon University

12:30  Luncheon
DAY TWO  
Thursday, December 11th, 2014

1:45  
**Transforming Clinical Development Through Analytics**  
- Identifying needs and solutions for analytical data storage, management, and integration  
- Uncovering clinical data challenges when outsourcing trials to CROs  
- Optimizing data analysis when capturing data from electronic data capture (EDC), clinical trial management systems (CTMS), electronic patient reported outcomes, and electronic health records (EHR)  
- Determining actionable analytics that are possible once data is attained and aggregated  

**Ben McGraw, Vice President of Marketing and Strategy,**  
**COMPREHEND SYSTEMS**

2:30  
**Case Study: Apply Real-World Metrics to a Clinical Trial Startup**  
- Discovering how rapid change in corporate priorities drive a transformation in development operations - Study Startup Acceleration Project  
- Uncovering data and leveraging metrics around Clinical Trial Agreements to ensure quality deliverables in the Clinical Study Contracts FSP relationship

3:15  
**Networking & refreshment break**

3:45  
**Use Certification as a Link to Site Performance**  
- Understanding how certification of clinical research staff can impact site performance  
- Identifying key data points related to certification  
- Uncovering ways certification can be used for performance indication/business development at the site level

**Morgean Hirt, Director of Certification,**  
**ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS**

4:30  
**Day 2 Concludes**

DAY THREE  
Friday, December 12th, 2014

8:00  
**Continental breakfast**

9:00  
**Chairperson's opening remarks**  
**David Zuckerman, Co-Owner, MCC**

9:15  
**Case Study: Discover and Implement Successful Uses of Clinical Dashboard**  
- Establishing a dashboard foundation to proactively execute metrics  
- Understanding and prioritizing key measurement factors to drive efficient metrics-based study delivery  
- Gaining successful change management approval  
- Aligning information compliance to drive quality aspect of dashboard  
- Incorporating track and support metrics to dashboards with the utilization of a Root Cause Analysis

**Jane Fang, R&D IS Lead for Clinical Business Analysis and Management, MEDIMMUNE**  
**Ron Bourque, R&D IS Sr. Manager for Clinical Business Analysis, MEDIMMUNE**

10:00  
**Leveraging Predictive Analytics and Risk Based Monitoring (RBM) to Generate Actionable Insights**  
- Utilizing a technology roadmap and vision to drive business decisions in clinical trials management  
- Establishing systems, best practices (TransCelerate), and methods that set the foundation for RBM  
- Understanding and executing dynamic source data verification with centralized statistical monitoring  
- Measuring the effectiveness of RBM implementation in the clinical enterprise  
- Managing trials and centralized statistical monitoring: live demo

**Haranath Gnana, Practice Area Leader & Head of European Operations, SAAMA TECHNOLOGIES**  
**Nikhil Gopinath, Clinical Solution Lead, SAAMA TECHNOLOGIES**

10:45  
**Networking & refreshment break**

11:15  
**Panel Session: Uncover Ways to Utilize Metrics to Enhance the Quality Management of Multiple Clinical Trial Aspects**  
- Laying the groundwork: The evolution of quality metrics  
- Identifying the value in using internal or external quality metrics systems  
- Realizing the science that exists behind within the quality of clinical trial metrics

11:45  
**Identify Quality, Regulatory, and Risk Metrics From a Therapeutic Drug Standpoint**  
- Leveraging Risk Based Monitoring methodologies and discovering Risk Based Auditing techniques  
- Utilizing and applying clinical trial data for site selection purposes  
- Harnessing the importance of metrics throughout an entire clinical trial pipeline

**Lydia Milne, Associate Director, Clinical Quality Assurance, ASTELLAS**

12:30  
**Luncheon**

1:30  
**Utilize a Site as a Partner in Metrics-Driven Performance to Increase Quality of a Trial**  
- Discovering strategies to proactively utilize metrics and benchmarking to collect data  
- Enhancing communicative ties between sites in order to drive excellence and increase performance improvement  
- Developing a report card system to compare and ensure patient satisfaction

**Howard Waxman, PhD, Director of Research, INVESTIGATIVE SITE**

2:15  
**Site Perspective: Utilize Site Metrics to Drive Proactive Site Improvement**  
- Discovering the issues that come along with the use of metrics  
- Enhancing sites in order to increase performance improvement  
- Understanding the difference between speed and quality improvements

**Dr. William Smith, MD, President, NEW ORLEANS CENTER FOR CLINICAL RESEARCH**

3:00  
**Chairperson’s Closing Remarks**  
**David Zuckerman, Co-Owner, MCC**

3:30  
**Conference concludes**
PAYMENT: Make checks payable to ExL Events, Inc. and write code C518 on your check. You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full by the conference date. Any discount applied cannot be combined with any other offers and must be paid in full at the time of order. Parties must be employed by the same organization and register simultaneously to realize group discount pricing options. Group discounts available to individuals must be registered simultaneously and employed by the same organization.

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

SAVE 15%
Can only send three? You can still save 15% off of every registration. To find out more about how you can take advantage of these group discounts, please call 212-400-6240.

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Questions? Comments?
Do you have a question or comments that you would like to be addressed at this event? Would you like to get involved as a speaker or discussion leader? Please email Conference Producer, Brendan Weiss at bweiss@exlpharma.com.
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