10th Clinical Performance Metrics & Benchmarking Summit
Utilizing Foundational Metrics in a Heavily Data Driven Environment to Ensure High Quality and Efficient Clinical Trials

December 4–5, 2013 • The Inn at Penn, A Hilton Hotel • Philadelphia, PA

NEW FOR 2013

- Find out what metrics standards the industry is moving toward and know which areas the industry is focusing on
- Determine the right metrics to better understand and predict site performance and reduce later costs from getting the right sites from the start
- Gain effective strategies for customized approaches to partnership metrics to hold third party vendors accountable
- Hear from a small company on how to develop in-house clinical recruitment metrics to track recruitment spending and results

NEW PRE-CONFERENCE WORKSHOP
STRATEGIES TO EFFECTIVELY IMPLEMENT RISK-BASED MONITORING
Find out which members of staff need to be involved to put risk-based monitoring in place, know what quality systems need to be in place as a foundation to execute risk-based monitoring and learn how to set tolerance limits and be held to account in the future.

David Zuckerman, Chief Executive Officer, Metrics Champion Consortium

FEATURED SPEAKERS INCLUDE

Grant Morgan, Senior Director, Global R&D Metrics, Productivity and Resource Management, Allergan
Will Chang, JD, Director, Clinical Operations, Tobira Therapeutics, Inc.
Christine Pierre, President, Society for Clinical Research Sites
Kathy Stoakes, RN, BSN, Associate Director, Clinical Operations, Daiichi-Sankyo
Peter Thadeio, Associate Director, Portfolio Analysis, Pfizer
Abigail R. Kennedy, PhD, Sr. Manager, Clinical Operations, XOMA (US) LLC
Caterina Whalen MPH, Senior Clinical Program Manager, Teva Pharmaceuticals
Liz Wool, President, QD—Quality and Training Solutions, Inc.

WITH SUPPORT FROM

Register for this conference and receive a complementary CRO Quality Benchmarking — Phase II/III Service Providers (2013) report courtesy of Industry Standard Reports!

For More Information Call 866–207–6528 | www.exlpharma.com/metrics
Get armed with a toolkit of metrics strategies being utilized across the industry to track and measure clinical performance to ensure and drive forward clinical efficiency and high quality as part of the larger business improvement plan.

R&D productivity continues to remain in a downturn at the same time that budgets remain tight. In a culture of doing more with less, metrics have never been more critical to assess performance and ensure quality and efficiency. As such, across the industry clinical operations professionals are looking to new methods to measure performance and drive quality, including quality agreements and partnership metrics.

Are you confident that you’ve selected the right metrics to measure and assess clinical performance to identify areas for improvement to improve quality, increase efficiency and maximize performance?

ExL Pharma’s 10th Clinical Performance Metrics and Benchmarking Summit is the premier event for gaining best practice strategies to maximize performance, improve operational quality and efficiency while achieving time and cost savings. Hear from key leaders in pharma to find out how risk is being assessed and managed in clinical development and how meaningful metrics are being identified and measured to drive quality, efficiency and process improvement.

WHAT WILL YOU GAIN FROM THIS YEAR’S SUMMIT?

- Strategies to effectively put risk-based monitoring into place
- A comprehensive understanding of the metrics standards the industry is moving toward
- Quality metrics to evaluate trial compliance to be prepared for inspection
- Tried and tested metrics to hold third party vendors accountable
- An understanding of the right metrics to better understand and predict site performance
- A risk assessment toolkit to ensure quick and efficient study start up

Return to your organization confident that you can select the most critical metrics and narrow down aggregate data to focus on the most important information to drive forward quality and continuous improvement while achieving efficiencies and monetary savings.

I look forward to welcoming you to Philadelphia in December!

Best wishes,

Marissa Alvord | Conference Production Director
malvord@exlpharma.com

WHO SHOULD ATTEND?

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

- Clinical Operations
- Study Management
- Metrics and benchmarks
- Clinical Development & Project Management
- Quality Assurance
- Clinical Planning and Outsourcing
- Clinical Research and Affairs
- Data Management
- Clinical Studies
- Trial Compliance
- Process Improvement
- Site Performance Management

SESSION SPOTLIGHT

PART TWO CASE STUDY

Todd Johnson, MPH, MBA, Global Head of Business Information Management, Astellas Pharma Global Development, Inc. returns to the conference to present a follow up to his case study last year. Find out lessons learned from the global roll out of a KPI dashboard and how to work with cross-organizational teams to implement process improvement activities.

SPONSORSHIP AND EXHIBITING OPPORTUNITIES

Do you want to spread the word about your organization’s solutions and services to potential clients who will be attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event, or distribute promotional items to attendees. ExL Pharma will work closely with you to customize a package that will suit all of your needs.

Learn more about these opportunities by contacting:

Eric Morrin, Business Development Manager
(212) 400–6228 | emorrin@exlpharma.com
DAY 1 | WEDNESDAY, DECEMBER 4, 2013

PRE-CONFERENCE WORKSHOP

8:00 Registration and Continental Breakfast for Workshop Participants

9:30 Strategies to Effectively Implement Risk-Based Monitoring

The FDA is advising the industry to move toward risk-based monitoring, which will result in cost savings and increased efficiency. The cost of monitoring is the single largest cost of running a clinical trial and effective implementation of risk-based monitoring will yield in significant cost savings, increased efficiency and increased operational quality. How can you effectively establish risk-based monitoring?

This workshop will help you to:
- Know which members of staff to have around the table to put risk-based monitoring in place
- Establish and identify quantitative and qualitative risks to perform quantitative and qualitative risk assessments

12:30 Lunch for Workshop Participants

MAIN CONFERENCE BEGINS

12:30 Registration Opens for Conference Attendees

1:30 Chairman’s Introduction and Welcome

David Zuckerman, Chief Executive Officer, Metrics Champion Consortium

1:45 PANEL DISCUSSION | What Metrics Standards is the Industry Moving Toward?

- How do you utilize metrics to get a better understanding of what is going on?
- What are the various metrics standards being established and how are the standards being developed?
- Which areas is the industry focusing on?
- What is the best approach to metrics for vendors?

Nancy Dynes, Metrics Consultant, Global Medical Quality, ELI LILLY AND COMPANY
Christine Pierre, President, SOCIETY FOR CLINICAL RESEARCH SITES
Linda Sullivan, Chief Operations Officer, METRICS CHAMPION CONSORTIUM
Kevin Olson, Chief Executive Officer, INDUSTRY STANDARD REPORTS

2:45 INTERACTIVE DISCUSSIONS | How Are You Benchmarking Site Selection, Study Initiation and Patient Enrollment?

- Based on your therapeutic area and business model, what benchmarks are you using?
- Who do you reference for benchmarks? How do you reference and how are you using the information?
- How do you measure your site selection and patient recruitment against industry benchmarks?
- What would you like to measure that you’re not currently able to measure? What are you doing to try to get there?

Liz Wool, President, QD—QUALITY AND TRAINING SOLUTIONS, INC.

3:25 Networking & Refreshment Break

3:55 CASE STUDY | Survey Public Data to Benchmark Clinical Trials Against Industry

- Tap into publicly available data and extract pertinent information to better understand trials
- Gather and collate widespread data on the length and locations of trials
- Geo-tag studies to get a better sense of inclusion and exclusion criteria to find out where things are going
- Utilize this information for forward planning and portfolio development

Peter Thadeio, Associate Director, Portfolio Analysis, PFIZER

4:35 Identify Site Selection Metrics to Pick the Right Site from the Start to Avoid Later Costs

- Determine the right metrics to better understand and predict site performance in a particular therapeutic area
- Gather and collate a range of historical data for more accurate site selection
- Reduce trial costs by finding the right sites from the start

Grant Morgan, Senior Director, Global R&D Metrics, Productivity and Resource Management, ALLERGAN

5:15 Close of Day One

For More Information Call 866-207-6528 | www.exlpharma.com/metrics
8:00  Continental Breakfast for Conference Participants

9:00  Chairperson’s Day Two Welcome and Day One Recap

David Zuckerman, Chief Executive Officer, Metrics Champion Consortium

9:15  Utilize Risk Assessment Tools to Ensure a Timely and Efficient Study Start Up Through Closeout

- Map out an individual study start up to identify potential problems
- Examine the tools that can be used to assess risk in study start up
- Establish metrics to determine which sites will be high and low enrollers
- Reduce study costs by up to 20% by focusing on high enrollers and overcome industry standards of one third of sites being non-enrollers
- Implement a strategic approach to verify drugs are on site and stored properly, workforces are trained and that a monitoring system is in place for a global trial
- Ensure robust and scalable processes are in place to manage site contracts, budgets, central documents and implementation and management of TMF for a quick and efficient study start up
- Monitor data cleaning status by partnering with Biometrics to ensure rapid data freeze and data lock activities

Will Chang, JD, Director, Clinical Operations, TOBIRA THERAPEUTICS, INC.

10:00  CASE STUDY | Small Company Solution: Building an In-House Clinical Recruitment Metrics System

- In today’s clinical environment where sponsors are competing to recruit subjects, and subjects are savvier than ever, what is the best way to design, implement and assess a clinical recruitment strategy?
- Hear about the recruitment experience at a small company that led to development of an in-house clinical recruitment system
- Identify key players involved and roll-out a system for clinical recruitment metrics to track recruitment spending and results
- Assess the pros & cons and cost-effectiveness of the simple metrics used for analysis of the system
- Determine whether a hands-on, robust in-house clinical recruitment system is a viable solution for small to large companies

Abigail R. Kennedy, PhD, Sr. Manager, Clinical Operations, XOMA (US) LLC

10:45  Morning Networking and Refreshment Break

11:15  CASE STUDY | Develop and Implement Key Quality Indicators & Performance Metrics for Robust Quality Oversight

- Understand what high quality Key Performance Indicators mean to you and your clinical study
- Strategies for clinical study quality oversight using key quality indicators and performance metrics
- Build a compliant statement of work

Kathy Stoakes, RN, BSN, Associate Director, Clinical Operations, DAIICHI SANKYO, INC.

12:00  Effective Partnership Metrics: From Governance Structures to Quality Agreements, Create a Customized Performance Management Approach

- Determine the different metrics needed for a study and for a partnership and come to a common definition of metrics with providers
- Utilize key relationship indicators and quality metrics to hold partners accountable
- Overcome challenges of linking data sources from different entities for efficient sharing of data and systems

Ken Schiff, President and Owner, QUALITY RISK MANAGEMENT ASSOCIATES, LLC

12:45  Lunch

1:45  CASE STUDY | Utilize KPI Dashboards to Drive Process Improvement

- Lessons learned from the successful global roll out of a KPI dashboard
- Identify areas requiring attention for project intervention and process improvement
- Drive change management, ensure staff are trained to overcome resistance and establish dashboard utilization
- Assess KPIs for inclusion and removal
- Work with cross-organizational teams to implement process improvement activities

Todd Johnson, MPH, MBA, Global Head of Business Information Management, ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.

2:30  Establish Metrics to Assess Trial Compliance to be Proactive and Prepared for Inspection

- Identify key areas that will be subject to audits and inspections
- Create quality data metrics when working in more complicated niche therapeutic areas
- Know which documentations must be in place and ensure sites are abiding by procedures
- Create a checklist to ensure you’re accomplishing everything that is absolutely necessary and that risks are managed and mitigated

Caterina Whalen MPH, Senior Clinical Program Manager, TEVA PHARMACEUTICALS
3:15 Chairperson’s Closing Remarks

David Zuckerman, Chief Executive Officer, Metrics Champion Consortium

3:30 Conference Concludes

ATTENDEE BREAKDOWN

INDUSTRY

- 38% PHARMA
- 14% SOLUTION PROVIDERS
- 12% R&D
- 10% BIOPHARMA
- 10% CRO
- 10% EDUCATION
- 6% BIOTECH

SENIORITY

- 55% DIRECTOR
- 25% MANAGER
- 10% ANALYST
- 4% SPECIALIST
- 4% EXECUTIVE

89%

CLIENT RETURN RATE TO EXL PHARMA’S METRICS & BENCHMARKING SUMMIT

VENUE

The Inn at Penn, a Hilton Hotel
3600 Sansom Street
Philadelphia, PA 19104
1–800–231–4587

If you require overnight accommodations, please contact The Inn at Penn, a Hilton Hotel at 1–800–231–4587 to book your room. ExL has reserved a block of rooms at a discounted rate for conference participants. Please mention “ExL’s December Meeting” to take advantage of the discount. You must book your room by November 20, 2013 to be eligible for the discounted rate. Please book your room early, as the rooms available at this rate are limited.
5 WAYS TO REGISTER

ExL Events, Inc.
494 8th Ave, Fourth Floor
New York, NY 10001

registration@exlpharma.com
866–207–6528
888–221–6750

www.exlpharma.com/metrics

GROUP DISCOUNT PROGRAMS
 Offers cannot be combined, early bird rates do not apply. To find out more on how you can take advantage of these group discounts, call 866–207–6528.

Save 25% 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 4 at one time).

Save 15% per person when registering three
Can only send three? You can still save 15% off of each registration.

REGISTRATION FEES

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Register by Friday, October 25, 2013
Conference + Workshop: $2095
Conference Only: $1795

STANDARD PRICING
Register after Friday, October 25, 2013
Conference + Workshop: $2295
Conference Only: $1995

ONSITE PRICING
Conference + Workshop: $2395
Conference Only: $2095

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To receive a refund or voucher, please fax your request to 888–221–6750 or call 212–400–6240.

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