EXECUTIVE SUMMARY

10th
Clinical Performance Metrics & Benchmarking Summit
INTRODUCTION

If you weren’t able to join us this year, here is what you missed at ExL Pharma’s 10th Clinical Performance Metrics & Benchmarking Summit...

With a focus on “utilizing foundational metrics in a heavily data driven environment to ensure high quality and efficient clinical trials,” the 10th annual summit was held Dec. 4-5 in Philadelphia, recognizing that budgets continue to remain tight and that metrics are more important than ever in the culture of doing more with less. Across the industry, pharma looks to quality agreements and partnership metrics to drive quality while top leaders champion industry standards for benchmarking.

Questions posed at summit included: What kind of savings will you realize when you implement site selection metrics? Are you confident that you’ve selected the right metrics to measure and assess performance to identify areas for improvement to enhance quality, increase efficiency and maximize performance?

The conference brought together representatives from pharmaceutical, biotech, medical device and clinical research companies with responsibilities in clinical operations, metrics and benchmarks, quality assurance, clinical research, data management, trial compliance and more.

Topics covered at the two-day event included industry metrics standards, implementing risk-based monitoring, developing/implementing key quality indicators and performance metrics, utilizing risk assessment tools, identifying site selection metrics, a variety of case studies and more.

Following are session summaries and highlights from the 2013 conference...
PRESENTATIONS

Todd Johnson of Astellas shared “Implementation of a KPI Dashboard within Global Development Operations,” noting that their team was attempting to validate the work of clinical development to senior management, measure progress, highlight areas needing additional attention and change behaviors. This involved better understanding company data, measuring change, reporting and focusing on process improvement. Rather than error-prone spreadsheets, dashboard implementation led to metric and KPI identification, data quality and compliance assessment, a pilot program, change management and future governance. The team learned that the most important information should always be placed in the upper left or center regions of the dashboard, bar graphs are the best for display while line graphs work well for encoding values on an internal scale, however, pie charts fail to display quantitative data effectively. Other lessons learned during rollout include: target smaller, related functions, track adoption and usage, provide access to external partners and limit access initially. The most well-defined KPIs are irrelevant if there is no data to populate them and dashboard credibility can be damaged by launching with inaccurate data so a focus on quality data is paramount. Dashboards should also be tied to a key process to showcase their utility.

A case study on “Small Company Solution: Building an In-house Clinical Recruitment Metrics System” was presented by Abigail Kennedy of Xoma. Despite considering a vendor for recruitment, Xoma recognized that managing a robust clinical recruitment strategy in-house is feasible even at a small company. A simple website forms the foundation of a robust recruitment strategy and developing simple metrics allows for the determination of the strategy’s cost-effectiveness. The team consisted of an in-house clinical research coordinator, marketing consultant, web programmers and designer, video designer and central call service. Early strategy involved a website to provide referrals as well as TV ads for local and national use and learned that different strategies worked for different sites. With overall success, next steps include scalable cost savings, determining if the same strategy will work for different phases and trials, finding strategies to further optimize online marketing and increasing the percentage of referrals coming from central recruiting.
PRESENTATIONS

Will Chang of Tobira Therapeutics shared a presentation on how to “Utilize Risk Assessment Tools to Ensure a Quick and Efficient Study Start up.” Critical elements are understanding risk assessment tools, mapping out the study start-up plan, choosing the appropriate assessment tools, establishing performance metrics, implementing a strategic approach for drug accountability, reducing study costs with vigorous vendor management, and ensuring robust and scalable processed for study management from start up through closure. In summary, he suggested using performance metrics appropriate for the organization, holding vendors accountable for quality and performance, and challenging the team to maintain or reduce study timelines and spending.

A case study on “Using a Text Mining Approach to Leverage Publicly Available Data” from Peter Thadeio of Pfizer focused on Clintrials.gov. Pfizer used Trial Tracker, an in-house tool developed to mine data from the site to showcase in a case study for osteoarthritis. With more than 150,000 trials in the database, data extraction requires some critical information to cull down data sets. In multiple cases, data has allowed the teams to gain a confidence level in their projections for timing of trials based on multiple variables. Further, new tools allow users to understand what a reasonable time for trial duration is, when and where trials are run, and alternate methods to visualize data to gain a different perspective.

“Effective Partnership Metrics: From Governance Structures to Quality Agreements, Create a Customized Performance Management Approach” was presented by Ken Schiff of Quality Risk Management Associates. Quality risk management (QRM) is a systematic process consisting of risk identification, risk assessment, risk mitigation, risk avoidance/reduction, and communication; it supports better decision-making by providing greater insight into risks and their impacts and helps in making proactive decisions. The objective of quality risk management is to ensure patient safety and data integrity as expectations of quality continue to increase across the industry. The new model detects systematic quality issues, rather than just individual issues, assessing quality data in a more frequent and focused manner. Benefits include early detection, broader reach and better insights. Analytical tools allow for ongoing risk monitoring, and a best practice database supports decision-making and reduces costs.
Finally, Caterina Whalen of Teva Pharmaceuticals shared information on how to “Establish Metrics to Assess Trial Compliance to be Proactive and Prepared for Inspection.” The delivery of clinical trials has three core components – time, cost and quality – and compliance falls into the quality category. Compliance categories include oversight, monitoring quality, site issues and safety. Change management, communication and training are also key components of the process.
FOR MORE INFORMATION

ExL Pharma’s 11th Clinical Performance Metrics and Benchmarking Summit is the premier event for gaining the absolute best practice strategies to significantly enhance a clinical trial. This platform will provide key insight to develop, utilize, and implement performance metrics in order to proactively measure and assess trial compliance.

As each pharmaceutical company is under constant pressure to deliver new drugs to the market faster than its competitor, it is crucial that trials are run efficiently, to a high quality standard, and on budget. This event will provide tools and solutions to drive proficiency and performance during clinical development. Attendees will leave with various methods being used across the industry to effectively track and measure clinical performance.

WHO SHOULD ATTEND:
This conference is designed for representatives from pharmaceutical, biotech, clinical research companies, and academic research organizations 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

For more information on this conference, please visit:
www.exlpharma.com/metrics

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