DATA INTEGRITY FOR CLINICAL RESEARCH

SUMMIT

Understand the Most Important Trends and the Future Direction of Clinical Data Integrity

MAY 22-23, 2017 | HYATT REGENCY MORRISTOWN | MORRISTOWN, NJ

CONFERENCE CHAIR:

Leslie Sam
Director, Global Quality Systems, Safety, Efficacy and Customer Information
ELI LILLY AND COMPANY

KEY TAKEAWAYS

- Understand regulatory guidances and their relationships with data quality and data integrity
- Discuss the management of data quality using a risk-based approach to detect risks
- Hear from pharmaceutical companies that have successfully ensured data integrity in clinical trials
- Master how to plan and check for data integrity
- Manage the complete life cycle of data by establishing procedures and best practices

FEATURED SPEAKERS:

Robert J. Boland
Associate Director, Emerging Science and Innovation Strategy
JOHNSON & JOHNSON

David Fryrear
Senior Director, Clinical and Pharmacovigilance QA
ABBVIE

Molly Rodgers
Senior Immuno-Oncology Data Lead
BRISTOL-MYERS SQUIBB

Angel Amaya
Senior Clinical Research Associate
NOVARTIS

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Register today ☎ 866-207-6528  ⌘ www.exlevents.com/dataintegrity
DEAR COLLEAGUE,

In a life science organization, data is key! Data can come into an organization through many avenues, but it’s important to understand where the data came from, the level of quality and its role in reporting clinical research.

This is especially true for a clinical trial, where you need to ensure the integrity of data from its inception to archival. Given the importance of valid data, clinical research and data professionals need to manage the way they conduct trials throughout their life cycles. Achieving and maintaining data integrity ensures the results of clinical trials are based on high-quality data, which helps determine the outcomes of these clinical trials.

ExL Events’ Data Integrity for Clinical Research Summit, taking place on May 22-23, 2017 at the Hyatt Regency Morristown in Morristown, NJ, will feature 14 educational sessions and panels from leading industry professionals showcasing data integrity successes and challenges. Over the course of two days, attendees will closely examine current trends and the future direction of data integrity, and have the opportunity to network with industry thought leaders and peers from other organizations.

Conference attendees will learn how to:
- Gain a better understanding of what data integrity means in clinical research
- Ensure data integrity by developing standard procedures for conducting clinical research
- Minimize risks in clinical trials by following best practices for safeguarding data integrity
- Apply other companies’ strategies, processes and tools for monitoring data integrity to their own businesses

I look forward to welcoming you to Morristown, NJ this spring!

Sincerely,

Kelly Osmulski
Conference Production Director
ExL Events, a Division of Questex, LLC
kosmulski@exlevents.com

WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical, biotech, medical device and clinical research companies with responsibilities in the following areas:
- Data Integrity
- Clinical Quality/Data
- Clinical Operations
- Clinical Research
- Paper Monitoring
- Quality Assurance/Quality Control
- Document/ Data Management
- IT
- Validation
- Compliance
- Quality Risk Management
- Regulatory Affairs
- Auditing

The event is also relevant to clinical QA, compliance and operations professionals from:
- Quality Service Providers and Consulting Companies
- CROs
- Data Management and Software Vendors
- Safety Reporting Vendors

VENUE NAME

Hyatt Regency Morristown
3 Speedwell Avenue
Morristown, NJ 07960

To make reservations, please call 1-800-233-1234 and request the negotiated rate for ExL’s May Meetings. The group rate is available until Monday, May 1, 2017. Please book your room early, as rooms available at this rate are limited.

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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 Events will work closely with you to customize a package that will suit all of your needs. To learn more about these opportunities, please contact Dor Peled, Business Development Manager, at 917-258-5159 or dpeled@exlevents.com.

Register today 866-207-6528 www.exlevents.com/dataintegrity
Gain a better understanding of what data integrity means in clinical research.

Explain what “ensuring data integrity” means and how data is generated from multiple systems.

Shrinivas Savale, Consultant, TORRENT PHARMACEUTICALS

Understand that nonadherence injects errors into clinical trials, leading to inaccurate results.

Recognize the widely accepted truth that subjects and patients are poorly compliant with medication instructions.

Discuss strategies for applying nonadherence data that can be quantified and used as a source of statistical power.

Explore ROI from monitoring adherence.

Allan Wilson, President, INFORMATION MEDIARY CORPORATION

Verify changes that occur in your clinical research and who controls the paper format.

Validate electronic systems are being used as intended in audit trails and other processes.

Develop ways to verify data and analyses in a study report.

Analyze data consistency in the complete life cycle of data.

David Fryrear, Senior Director, Clinical and Pharmacovigilance QA, ABBVIE

Sameer Thapar, Assistant Professor and Advisor, Drug Safety and Pharmacovigilance, RUTGERS UNIVERSITY

Modernize a laboratory to comply with data integrity standards.

Transition legacy equipment to a consistent platform for interoperability.

Explore integrated risk-based approaches to maintain data in your organization.

John Hannon, Global Business Lead, Automation and IT, COMMISSIONING AGENTS, INC

Monday, May 22, 2017 — Day One

8:00 Registration and Continental Breakfast

8:30 Chairperson’s Introduction
Leslie Sam, Director, Global Quality Systems, Safety, Efficacy and Customer Information, ELI LILLY AND COMPANY

8:45 Regulatory Guidance and Relationships with Data Quality and Data Integrity: Perspectives on Clinical Studies for ANDAs
- Gain a better understanding of what data integrity means in clinical research
- Clarify the relationship between data quality and data integrity
- Explain what “ensuring data integrity” means and how data is generated from multiple systems

Shrinivas Savale, Consultant, TORRENT PHARMACEUTICALS

9:30 IMC Perspective on Data Integrity
- Understand that nonadherence injects errors into clinical trials, leading to inaccurate results
- Recognize the widely accepted truth that subjects and patients are poorly compliant with medication instructions
- Discuss strategies for applying nonadherence data that can be quantified and used as a source of statistical power
- Explore ROI from monitoring adherence

Allan Wilson, President, INFORMATION MEDIARY CORPORATION

10:15 Networking Break

10:45 Panel: The New Draft MHRA GxP Data Integrity Definitions and Guidance for Industry
- Learn about the new draft MHRA definitions and guidance for the industry
- Discuss the main intent of the regulatory requirements
- Understand the core elements of an effective data governance approach across all GxP sectors

Ana Sharma, Global Head, Strategy and Operations for Clinical Development Quality, NOVARTIS

Bodo Lutz, Global Clinical Quality Assurance, Compliance and Data Integrity Officer, NOVARTIS

11:30 Panel: Plan for Prevention and Check for Data Integrity in Your Organization
- Hear perspectives in the steps to check for data integrity
- Study best practices for facing the challenges that occur in pharmaceutical companies
- Introduce ways to make sure you have followed the correct procedures in your research
- Focus on how FDA inspectors check for data integrity

Kerrick Wilson, Quality Assurance Manager, GLAXOSMITHKLINE

Jim Myers, Executive Director Quality Assurance and Compliance, IONIS PHARMACEUTICALS

12:15 ALOCA: A Company’s Perspective on How to Ensure Better Data Integrity Overall
- Contextualize the ALOCA procedure and its role in clinical trials
- Determine how to make corrections in a compliant manner
- Examine newer and evolving technologies

Angel Amaya, Senior Clinical Research Associate, NOVARTIS

5:45 Conclusion of Day One
8:00 Continental Breakfast

8:30 Chairperson’s Recap of Day One
Leslie Sam, Director, Global Quality Systems, Safety, Efficacy and Customer Information, ELI LILLY AND COMPANY

8:45 Endgame Quality Control: Delivering on the Promise of Integrity
- Recognize challenges in maintaining data integrity through submission
- Navigate handoffs, versioning and pain points
- Discover ways to control data integrity through submission
Anna Capaldi, Quality Control Submission Lead Biosimilars, PFIZER

9:30 Optimizing Data Integrity by Ensuring Compliant Documentation of All Data Entries and Changes
- Evaluating the results from site audits indicating confusion about how changes should be tracked, documented and escalated
- Defining an internal quality approach with tools and systems
- Communicating your quality expectations to your CRO and site partners to guarantee data integrity
- Conducting a gap analysis of processes to identify issues surrounding data integrity and develop process improvement measures
Nathalie Bourgouin, PMP, Director, SKILLPAD

10:15 Networking Break

10:45 A Sponsor’s Perspective on Data Integrity
- Discuss the accountability of data integrity
- Establish data validation rules to ensure data integrity control and values
- Walk through how to comply with FDA inspection requirements
Bodo Lutz, Global Clinical Quality Assurance, Compliance and Data Integrity Officer, NOVARTIS

11:30 Data Integrity in Clinical Research
- Understand how remote data entry, electronic data collection and changes to data monitoring have improved the integrity of data collected
- Identify timesaving processes and procedures that have been implemented to advance data integrity
- Assess data integrity strategies, benefits and challenges from the perspectives of subjects, sites, CROs and pharma
Barbara Skinn, Operations Portfolio Lead, Global Clinical Operations, BRISTOL-MYERS SQUIBB
Molly Rodgers, Senior Immuno-Oncology Data Lead, BRISTOL-MYERS SQUIBB

1:15 Clinical Trial Data Transparency from Site to Sponsor
- Review approaches to achieve full data transparency to bring credibility and trust
- Communicate how to achieve data transparency at large
- Discuss how to ensure that research practices are transparent and comply with laws, regulations and guidelines
- Examine changes in the use of clinical data in disclosure and transparency landscapes
Debra Mayo, Vice President, Global Scientific Communications, TEVA

1:45 Keynote Presentation: It’s My Data and I’ll Share if I Want To
- Explore a major barrier to unlocking the true power of collaboration: the willingness and ability of major stakeholders to share data
- Hear about how today’s environment impacts the willingness of parties to share data
- Identify ways to overcome reluctance to data sharing and to protect and reward those who do
- Review new approaches to security, connectivity and interoperability, together with a new generation of “smart operations”
Greg Koski, President and Co-Founder, ALLIANCE FOR CLINICAL RESEARCH EXCELLENCE AND SAFETY (ACRES)

2:30 Networking Break

3:00 Enabling Near-Time Analysis of Exploratory Biomarker Data in Clinical Studies
- Understand the importance and challenges of enabling exploratory biomarker data analysis
- Examine various fit-for-purpose workflow approaches to automatically reconcile and be alerted of data quality issues
- Walk through an example of a complete workflow that enables biomarker scientists to start the analysis within the same day the biomarker data is made available in its native format
Irene Pak, Associate Director, Disease Area Information Science, BRISTOL-MYERS SQUIBB

3:30 Conference Concludes

“32% of drugs have a probability of making it to Phase 3 trials, and only one in 10 drugs overall actually makes it to market.”
—Clinical Leader, October 3, 2016

Register today 866-207-6528 www.exlevents.com/dataintegrity
Registration Fees for Attending ExL’s Data Integrity for Clinical Research Summit:

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Data Integrity for Clinical Research
MAY 22-23, 2017 | MORRISTOWN, NJ

Understand the Most Important Trends and the Future Direction of Clinical Data Integrity

Clinical Data Process  Data Integrity Guidance  Audits  Access