ADVERSE EVENT REPORTING AND SAFETY STRATEGIES SUMMIT

October 15-16, 2014
Hyatt at The Bellevue • Philadelphia, PA

Optimize Clinical and Post-Marketing Adverse Event Reporting while Developing Efficient Pharmacovigilance Strategies Within your Organization

OUR ESTEEMED FACULTY INCLUDES:

- BRUCE DONZANTI, PH.D, Head, US Drug Safety, GENENTECH
- HEIDE CUNNING, US Pharmacovigilance Officer, JANSSEN PHARMACEUTICALS
- DANIEL TRIPP, Director, Medical Quality Assurance, PFIZER
- MIKE SAUNDERS M.D., Senior Director, Clinical Drug Safety, ARRAY BIOPHARMA
- COLLEEN WALSH, Head, Safety and Benefit Risk Management Quality, BIOGEN IDEC
- BENNETT LEVITAN, M.D., PH.D., Director, Epidemiology, JANSSEN RESEARCH & DEVELOPMENT, JOHNSON & JOHNSON
- LISA BENAISE, M.D., M.P.H, Senior Medical Director, Head, Office of Medical Safety Evaluation Global Development Safety Evaluation Center, MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA

15+ Sessions Covering:

• Ways to handle safety reporting from solicited programs and social media
• Benefit-risk assessments to improve decision-making
• Signal detection within development drug safety and post-marketing adverse event reporting
• Risk management strategies to mitigate the occurrence and impact of adverse events from early phases to post-marketing
• Trends, key lessons learned and tools for global pharmacovigilance inspections
• Proactive pharmacovigilance in a global environment
Dear Colleague,

Adverse events are the pillars of pharmacovigilance and safety operations as we know them. They have been the drivers for developing safety databases, risk management plans, risk evaluation and mitigation strategies (REMS), benefit-risk assessments and periodic reports. Their collection and reporting has been instrumental in leading to preventative actions for marketing better and safer drugs.

This collection and reporting of adverse events is crucial for determining negative or positive safety signals and subsequent actions. As a result of this, safety departments across the world are exploring and implementing ways to improve safety reporting from clinical to post-marketing phases. Patient support/adherence programs are emerging as channels for collecting, reporting and assessing adverse events that arise from patient-industry interactions, and have drastically influenced the way drug safety and marketing departments interact with one another. In addition, pharmaceutical companies are going beyond safety assessments based on the evaluation of adverse events and are implementing benefit-risk assessments (taking into account benefits, risks, and the context of use of drugs) in order to improve decisions along the drug development process.

The Adverse Event Reporting and Safety Strategies Summit dives into the different ramifications of adverse event reporting in the context of benefit-risk assessments, real world data, risk management plans, signal detection, periodic reporting and solicited/unsolicited reports. The summit illustrates how different life sciences companies are working towards a better prevention, detection and assessment of adverse reactions to drive reporting and impact drug safety profiles.

I hope to see you in October to explore the different thought processes and safety strategies that industry experts are employing to make better-informed decisions within their pharmacovigilance operations!

Sincerely,

Katerina Leon

Katerina Leon,
Conference Production Director
kleon@exlpharma.com

VENUE:

Hyatt at the Bellevue
200 South Broad Street
Philadelphia, PA 19102

Room Reservations: To make reservations, please call 1-888-421-1442 and request the negotiated rate for ExL’s October Meetings. The group rate is guaranteed until September 23, 2014

Who Should Attend:

This conference is designed for professionals from pharmaceutical, biotech and medical device companies with responsibilities in the following areas:

- Pharmacovigilance
- Drug Safety
- Risk Management
- Safety Research/Epidemiology
- Pharmacoeconomics
- Medical Product Safety Assessment
- Regulatory Affairs
- Clinical Research
- Safety Surveillance
- Signal Detection
- Clinical Safety
- Patient/Medical Safety
- Medical Directors
- Health Outcomes
- Phase IV/Post Marketing Studies

Additionally this event is of interest to:

- Adverse Event/Case Management Service Providers
- Safety Database Providers For Case Management
- Clinical Research Organizations
- Service Providers For Drug Safety
- Healthcare/Pharmacovigilance Consultants
- Healthcare Translation Agencies

INTERESTED IN SPONSORSHIP & EXHIBITION OPPORTUNITIES?

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

To learn more about these opportunities, contact Eric Morrin, Business Development Manager at 212-400-6228 or emorrin@exlpharma.com
9:00 CHAIRPERSON OPENING REMARKS
Bruce Donzanti, Ph.D, Head, US Drug Safety, GENENTECH

9:15 THE IMPACT ON SAFETY MANAGEMENT AND CLINICAL TRIAL PROCESSES OF ADVERSE EVENTS THAT ARISE FROM INTERVENTIONAL AND NON-INTERVENTIONAL STUDIES
» Strategies for mapping data that arises from interventional vs. non-interventional studies and the impact on global safety reporting requirements
» Understand the inclusion of safety data that arises from interventional and non-interventional studies in health authority periodic reports, protocols, CSRs and clinical trial registry requirements
Heide Cunning, US Pharmacovigilance Officer, JANSSEN PHARMACEUTICALS

10:00 TRIALS, TRIBULATIONS AND TRIUMPHS TWO YEARS INTO THE “NEW” EUROPEAN PHARMACOVIGILANCE LEGISLATION
» Discuss select Good Pharmacovigilance Practice (GCP) modules and one company’s approach to interpretation and implementation
» Examine the challenges faced in implementing the legislation
» Hear the successes and lessons learned over two years of implementation
» Discuss the experience with PV inspections in the post-EU legislation environment
Colleen Walsh, Head, Safety and Benefit Risk Management Quality, BIOTEN IDEC

10:45 NETWORKING BREAK

11:15 A MODEL FOR AN EARLY DEVELOPMENTAL CORE RISK MANAGEMENT PROGRAM
» Discuss when pharmacovigilance departments should get involved in developing risk management programs
» Highlight the advantages to establishing a developmental risk management plan through all phases leading up to preparations for submission
» Discuss developmental risk management plan accountability and working with a Safety Management Team to achieve results
Rudolph Valentino, Director, Risk Management Scientific Lead, Risk Management Center of Excellence, JANSSEN PHARMACEUTICAL COMPANIES OF JOHNSON & JOHNSON

12:00 LUNCHEON

1:15 EPIDEMIOLOGIC METHODS AND NON-INTERVENTIONAL STUDY DESIGN FOR SIGNAL DETECTION
» Learn about the role of epidemiology in signal detection
» Examine potential data sources for contextualizing data
» Data mining of Electronic Health Records (EHR) as a fundamental tool for the detection of adverse events
» Interpretation of findings from non-clinical studies and real-world data studies
» Emerging trends in epidemiologic evaluations
Lisa Weiss, Director, Epidemiology, Worldwide Safety and Regulatory Strategy, PFIZER

2:00 IMPORTANCE OF SIGNAL DETECTION WITHIN BOTH DEVELOPMENT DRUG SAFETY AND POST-MARKETING ADVERSE EVENT REPORTING
» Considerations to perform signal detection during both clinical development and post marketing stages
» Examine collection and analysis of safety data to drive preventative actions
» Learn about signal detection from data collection through product safety committees, label committees and subsequent label change implementation
» Explore best practices for signal detection in the potential of product separation between competitors
Mike Saunders M.D., Senior Director, Clinical Drug Safety, ARRAY BIOPHARMA

2:45 NETWORKING BREAK

3:15 EFFORTS AND BEST PRACTICES TO INCREASE ADVERSE EVENT REPORTING THROUGH PATIENT ADHERENCE AND PATIENT SUPPORT PROGRAMS
» Explore pharmaceutical post-marketing Customer Engagement Programs, relevant regulatory requirements, and their impact on consumer’s adverse event reporting
» Hear ways to improve existing oversight programs and decrease follow-ups within the case management workflow
» Examine the impact of the data that arises from solicited programs on safety operations and on the interactions with marketing departments within the same company
Arpad Simon, Head, Drug Safety, MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA

4:00 ASSESSMENT OF ADVERSE EVENTS FROM SOLICITED PROGRAMS AND SOCIAL MEDIA
» Learn about the relationship between patient support programs and the impact on drug safety risk profiles
» Expectations on the collection, assessment, and reporting of adverse events from FDA and EMA with regard to solicited programs
» Learn about the importance of incidental data vs. valid adverse events from patient support programs
» Explore the different strategies to drive a risk-based approach to assess adverse events and the validity of safety signals from various types of patient support programs and other solicited programs including social media
Bruce Donzanti, Ph.D, Head, US Drug Safety, GENENTECH

4:45 INDUSTRIES VIEW ON HOW TO HANDLE SAFETY REPORTING FROM SOLICITED PROGRAMS (PATIENT SUPPORT PROGRAMS, CUSTOMER ENGAGEMENT PROGRAMS) AND HOW THESE VIEWS DIFFER TO THE ONES FROM REGULATORY AGENCIES
» Industries view on practical ways to handle safety reporting from solicited programs
» How these views are similar or differ from current FDA and EMA regulations and what can industry provide from their experiences to help address any gaps between them and regulator’s expectations
Moderator:
Bruce Donzanti, Ph.D, Head, US Drug Safety, GENENTECH
Panelists
Arpad Simon, Head, Drug Safety, MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA
Heide Cunning, US Pharmacovigilance Officer, JANSSEN PHARMACEUTICALS
Katie Clifford, MBA, BSN, RN, Director, Standards & Collaboration Drug Safety & Public Health, GILEAD SCIENCES

5:30 CONCLUSION OF DAY ONE
INTTEGRATED PATIENT SAFETY RISK MANAGEMENT WHILE FOCUSING ON THE IMPORTANT RISKS
- Understanding the risk landscape of a product and prioritization of important risks
- Development and deployment of strategies to address risk in the context of the comparative benefit-risk balance
- Selection of methodologies to assess the effectiveness of risk minimization or mitigation

Michael Forstner, Head of Pharmacovigilance Europe, BOEHRINGER INGELHEIM

STRATEGIES AND BEST PRACTICES FOR COMPLIANT PERIODIC REPORTING
- Learn about the variation in content and timelines for periodic reporting in different regulatory environments
- Best practices for compliant and efficient reporting of aggregate data
- Discuss ways to understand patterns in aggregate data
- Explore the waivers that are in place to help companies consolidate their aggregate reporting requirements and whether this results in an increase/decrease of resources, efficiencies and productivity

Heidi Krenz, M.D., Senior Director, Drug Safety, SHIONOGI

REAL WORLD DATA AND THE IMPACT ON PHARMACOVIGILANCE OPPORTUNITIES, CHALLENGES AND STRATEGIES
- Discuss the opportunities to leverage real world data for safety evaluations and for the building and understanding of product safety profiles
- Highlight challenges and limitations of real world data derived from healthcare databases
- Explore ways to overcome limitations of real world data to maximize value

Michael Taylor, Global Head of Epidemiology for Oncology, GENENTECH

EXPLORING THE AVAILABLE OPTIONS USED BY COMPANIES TO OPTIMIZE PROCESSES AND DEVELOP EFFECTIVE RISK MANAGEMENT PLANS TO ACHIEVE PATIENT SAFETY AND REGULATORY COMPLIANCE
- How to create risk profiles for compounds based on clinical trial data, epidemiology studies and post marketing reports
- Discuss risk mitigation strategies for safety monitoring during the clinical trial and post marketing environment
- Explore efficient ways of signals detection and evaluation in different companies
- Discuss benefit-risk analysis methodologies

Moderator: Rakesh Dixit, Vice President, R & D, Global Head, Biologics Safety Assessment, MEDIMMUNE
Panelists:
Amy Sun, Director, Clinical Risk Management, Global Safety, MERCK & CO
Mike Saunders, Senior Director, Clinical Drug Safety, ARRAY BIOPHARMA
Lisa Benaise, M.D., M.P.H, Senior Medical Director, Head, Office of Medical Safety Evaluation, GDSEC, MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA

GLOBEAL SIGNAL MANAGEMENT STRATEGIES
- Points to consider for managing safety signals from identification through evaluation
- Practical considerations for an end-to-end signal management process
- Key messages from EU GVP Module IX

Leslie Killion, M.D., Senior Director Therapeutic Area Safety Head, Global Medical Organization, JANSSEN RESEARCH & DEVELOPMENT, JOHNSON AND JOHNSON
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Register before August 29

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If you cancel at any time after receiving the conference documentation, the voucher issued will be $395 less.

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