8th Annual
Pharmacovigilance, Drug Safety & Risk Management

Enabling Proactive Drug Safety through Enhanced Automation & Pharmacovigilance Practices

September 20-21, 2018
Philadelphia, PA

More Registration Details. Click Here!

Conference Chairperson:
Alexandre Kiazand, M.D.
Head Safety Science
AstraZeneca

Attending This Premier marcus evans Conference Will Enable You To:
• Improve Pharmacovigilance practices through innovation
• Leverage Artificial Intelligence and Machine Learning to minimize errors and improve data processing
• Automate PV practices to streamline risk assessment and data capture
• Enable predictive drug safety through a proactive risk management approach
• Ensure safety by improving reporting and monitoring of adverse drug events
• Incorporate data from digital channels and alternative methods for gathering patient experience
• Develop strategies for incorporating and enhancing pharmacovigilance in combination products
• Assess impacts of global regulatory changes to make adjustments to PV strategy
• Strengthen risk management & mitigation strategies throughout drug lifecycle

Who Should Attend: marcus evans invites C-Level Executives, EVPs, SVPs, VPs, Directors, Heads and other senior executives responsible for:
• Pharmacovigilance
• Drug/ Patient Safety
• Medical Product Safety Assessment
• Clinical Research
• Health Outcomes
• Risk Management
• Regulatory Affairs
• Data Analysis
• Pharmacoepidemiology
• Medical Information

Current Speakers Include:
Alexandre Kiazand, M.D.
Head Safety Science
AstraZeneca

Elizabeth Allee
Senior Director, Case Processing Center of Expertise
AbbVie

Linda Lum
Director, Global Pharmacovigilance and Epidemiology
Bristol-Myers Squibb

Deepa Venkataraman
Senior Director, Section Head, Drug Safety and Pharmacovigilance Operations
Pharmacyclics LLC, an Abbvie Company

Hal Ward
Executive Director, Drug Safety Surveillance
Kyowa Kirin

Kimberly Marcopul
Director, Drug Safety and Pharmacovigilance
Alkermes

Anupam Agarwal
Head, Global Drug Safety, Pharmacovigilance
Zogenix

Kathryn M. Connor, MD MHSc
Sr. Prin. Scientist Clinical Safety and Risk Management
Global Regulatory Affairs and Clinical Safety
Merck

Katherine Roberts
Vice President, Global Pharmacovigilance Operations and Systems Quality Management
Incyte

Tanya Taft
Vice President of Patient Safety
Fresenius Medical Care North America

Tamala Mallett Moore
Therapeutic Area Lead
Sanofi Pasteur

Richard Wolf
Head of Global Clinical Safety & Pharmacovigilance (GCSP) Regions & Pv Operations
CSL Behring

Jennifer Reiner
Director, Risk Management Product Lead, Worldwide Safety & Regulatory
Pfizer

Ellen Snyder
Senior Principal Scientist, Clinical Safety Statistics, Biostatistics & Research Decision Sciences
Merck

Kenneth J. Lipetz, PhD, MBA, HCLD
Global Patient Safety Medical and Benefit-Risk Management/ GSP Medical Process Owner / GSP Medical Business Advisor
Eli Lilly & Company

Drive Pharmacovigilance forward with innovative technologies and strategies to proactively manage risk

Increasing drug safety profile in clinical and post market with effective monitoring and risk minimization strategies.

Booking Info:
Amanda Pink | T: 1 312 894 6310
E: AmandaP@marcusevansch.com
8:00 Registration, & Morning Coffee

8:45 Chairperson’s Opening Address
Alexandre Kiazand, M.D.
Head Safety Science
AstraZeneca

BENCHMARKING PHARMACOVIGILANCE PRACTICES

9:00 Case Study
Establishing Best Practices for the Presentation of Adverse Drug Reactions in the Reference Safety Information
- Defining the data collection criteria for analysis of adverse reactions
- Developing a process to assess adverse events to define adverse reactions
- Incorporating regulatory guidance for updating the reference safety information
- Presenting adverse reactions in labels
- Examining presentation of safety information across several types of labels
Linda Lum, Director, Global Pharmacovigilance & Epidemiology
Bristol-Myers Squibb

9:45 Case Study
Reinforcing Comprehensive PV and Risk Management Strategies for Design & Development of Combination Products
- Identifying the similarities and differences of developing combination products vs. drugs
- Considering nuances in submission of combination products and overall regulatory expectations
- Re-examining perception of risk for combination products
Kenneth J. Lipetz, PhD, MBA, HCLD, Global Patient Safety Medical and Benefit-Risk Management/ GSP Medical Process Owner / GSP Medical Business Advisor
Eli Lilly & Company

10:30 Networking Break

11:00 Interactive Panel Discussion
Maintaining Global Compliance through Enhanced Regulatory Intelligence
- Developing strategies for reporting of signals for Non-Harmonized Countries
- Identifying ways to manage compliance within Non-Harmonized countries
- Maintaining global compliance through enhanced communication and understanding of reporting expectations
- Considering differences and similarities of timeframes associated with global regulations
Panelists:
Deepa Venkataraman, Sr Director, Section Head, Drug Safety & Pharmacovigilance Operations
Pharmacyclics, an Abbvie Company
Alexandre Kiazand, M.D., Head Safety Science
AstraZeneca
Linda Lum, Director, Global Pharmacovigilance & Epidemiology
Bristol-Myers Squibb
Kenneth Lipetz, Global Patient Safety Medical and Benefit-Risk Management
Eli Lilly & Company

11:45 Case Study
Discussing Aggregate Safety Assessment Planning in Drug Development
- Considering characterization of ongoing safety and the safety profile of developmental compounds
- Strengthening strategies for preparation for filings
- Understanding potential aggregate IND safety reporting
Kathryn M. Connor, MD MHSc, Sr. Prin. Scientist Clinical Safety and Risk Management Global Regulatory Affairs and Clinical Safety
Merck
Ellen Snyder, Senior Principal Scientist, Clinical Safety Statistics, Biostatistics & Research Decision Sciences
Merck

12:30 Luncheon

1:30 Interactive Roundtable
Spotting Opportunities and Developing Methods for Incorporating Innovation Solutions within PV Practice
- Discussing methods with incorporating automation
- Focusing innovation efforts around drug safety
- Examining lesson learned from incorporating automation in drug lifecycle
Alexandre Kiazand, M.D., Head Safety Science
AstraZeneca

LATEST TECHNOLOGICAL TRENDS FOR AUTOMATION & DATA CAPTURE

2:15 Case Study
Leveraging Machine Learning (ML) & Artificial Intelligence (AI) to Stay Up-to-Date in a Rapidly Changing Landscape
- Identifying available tools and solutions for ML and AI to ensure optimal program selection to meet internal needs.
- Considering ways to use ML and AI within PV and product lifecycle to ensure safety
- Easing the burden of PV individuals by leverage AI and ML
- Staying up to speed with the industry by using innovative technology solutions
- Considering cost associated with human error and effort to rationalize acquisition of ML & AI
Anupam Agarwal, Head, Global Drug Safety, Pharmacovigilance
Zogenix

3:00 Networking Break

3:30 Case Study
Integrating Automation in Individual Case Safety Report (ICSR) Processing – Selection, Lessons Learned, and Future State
- Examining reasons to automate
- Identifying the right technology to use
- Developing methods for prioritizing
- Discussing proof of concept projects and lesson learned
Elizabeth Allee, Sr. Director, Case Processing Center of Expertise
AbbVie

4:15 Case Study
Converting Safety Database to a Cloud Based System
- Overcoming challenges of moving a safety database to the cloud
- Comparing pros and cons of maintaining databases internally vs. externally on the cloud or other vendor programs
- Discussing lessons learned from leveraging a cloud based system
- Considering aspects of migrating data and benefits of having cloud accessibility
Katherine Roberts, Vice President, Global Pharmacovigilance Operations and Systems Quality Management
Incyte

5:00 Case Study
Creating a RPA/AI Roadmap for PV Operations within Mid-Sized Biopharma
- Identifying automation opportunities in Case Management
- Understanding how ready are we for AI/NLP
- Defining considerations in building your business case for automation
- Discussing thoughts about the future organizational model to establish and support automation solutions
Richard Wolf, Head of Global Clinical Safety and Pharmacovigilance (GCSP) Regions & Pv Operations
CSL Behring

5:45 Closing Remarks and End of Day One

More Registration Details. Click Here!

MARKETING INFO
For more information about the event or information on how to book, please contact: Amanda Pink, AmandaP@marcusevansch.com, 1 312 894 6310
Day Two | Friday, September 21, 2018

8:30 Registration & Morning Coffee

8:50 Chairperson’s Opening Address
Alexandre Kiazand, M.D.
Head Safety Science
AstraZeneca

INNOVATION & UPDATES IN PHARMACOVIGILANCE

9:00 Case Study
Identifying Innovative & Alternative Methods for Gathering Patient Experiences from Digital Channels
- Leveraging social media insights as patient data
- Using alternative avenues for collecting and understanding of patient experiences
- Utilizing mobile apps as Patient Support Programs
- Combining traditional and Big Data systems to build a more robust public health system

9:45 Case Study
Incorporating Pharmacovigilance Practices with Specialty Pharmacies
- Building tactics for establishing the AE reporting program in specialty pharmacies
- Developing parameters for patient safety within specialty pharmacies
- Meeting pharmacovigilance demands and regulations with specialty pharmacies

Deepa Venkataraman, Sr Director, Section Head, Drug Safety & Pharmacovigilance Operations
Pharmacycics, an Abbvie Company

10:30 Networking Break

11:00 Interactive Panel Discussion
Applying Digital Health & Data from Digital Channels for Reporting
- Clarifying methods for using information from digital channels and MedWatch
- Deciding how to use digital health in AE reporting
- Understanding ways to gather adverse events from the digital health arena
- Developing standards for qualifying and recording data from digital solutions

Panelists:
Anupam Agarwal - Head, Global Drug Safety, Pharmacovigilance
Zogenix
Alexandre Kiazand, M.D. - Head Safety Science
AstraZeneca

11:45 Case Study
Achieving Compliance by Implementing New Guidance on Combination Products
- Unpacking guidance on combination products to understand expectations for reporting
- Finding meaningful ways to execute requirements by discussing comments released on the guidance
- Implementing new rules by rethinking intake processes and case processing to be compliant
- Amending information sharing & reporting decision making
- Considering requirements in areas of safety reporting and aggregate safety reports

Tamala Mallett Moore, Therapeutic Area Lead
Sanofi Pasteur

12:30 Luncheon

1:30 Case Study
Building Optimal Partnerships for Outsourcing PV Functions
- Outsourcing research functions to CROs to streamline process
- Identifying tasks that can enhance PV procedures by being outsourced
- Considering all potential partners to ensure ideal source is leveraged
- Practicing quality management oversight to create success

Hal Ward, Executive Director, Drug Safety Surveillance
Kyowa Kirin

2:15 Case Study
Fortifying Surveillance and Monitoring to Ensure Safety for Marketed Drugs
- Developing and bolstering strategies for safety surveillance and quality in combination products post market
- Creating practices for dealing with spontaneous & aggregate reporting, risk assessment, & benefit-risk management
- Characterizing spontaneous reporting in order to understand the spontaneous reporting system
- Using benefit-risk post-market

BUILDING PROACTIVE & ROBUST RISK MANAGEMENT THROUGHOUT PRODUCT LIFECYCLE

3:00 Interactive Panel Discussion
Employing Methods for Proactive PV through a Predictive Safety Approach
- Predicting safety by preparing for potential safety issues
- Evaluating proactive & predictive drug safety measures to optimizing risk management & signal detection
- Focusing on the patient population to predict and mitigate risks rather than the drug itself
- Fostering a holistic view on drug safety through a proactive approach

3:45 Networking Break

4:15 Case Study
Developing Potential Risk Evaluation Mitigation Strategies (REMS) for Submission with a NDA/ BLA
- Generating a pro-active approach to risk management through REMS
- Understanding the inter-relationship with labelling and risk management
- Devising a systematic approach to risk management
- Incorporating operational considerations into REMS

Jennifer Reinert, Director, Risk Management Product Lead, Worldwide Safety & Regulatory
Pfizer

5:00 Case Study
Upgrading Product Quality by Improving Patient Benefit-Risk Management
- Reinforcing current benefit-risk analysis models with new tools to optimize decision making
- Enabling better benefit-risk decision making and risk minimization across product portfolios
- Understanding and clarifying risks and benefits through upgrades to product monitoring

5:45 Closing Remarks and End of Day Two

More Registration Details. Click Here!

DISCLAIMER
This agenda may be subject to change for reasons outside of our control. Marcus Evans, Inc. reserves the right to replace, substitute, or remove any speaker in the event of an emergency or any unforeseen situation in which a confirmed speaker is unable to attend the event. Marcus Evans, Inc. will make every effort possible to substitute a speaker in this circumstance with an equally qualified professional for the confirmed presentation. However, Marcus Evans, Inc. does not guarantee the possibility of replacement.
I find the 2 day event to be packed full of information to proactively assist current regulatory and strategic challenges in Pharmacovigilance.

Sanofi

Excellent content and organization.

AstraZeneca

Very informative and interesting while stayed focused in PV/Risk Management. I’m very impressed with the knowledge of the speakers.

Allergan

Diverse, well organized presentations by experienced people.

AbbVie

I really enjoyed and took lots of information back with me. Had ongoing changes discussed and future topics which made two days very interesting.

EMD Serono

Great forum for drug safety/PV, epidemiology & regulatory colleagues to collaborate and learn in a very focused forum.

Gilead Sciences