July 17-18, 2017 // Sheraton Philadelphia University City Hotel // Philadelphia, PA

eXL events 2017

Real-World Evidence Forum

Improve health outcomes through the analysis of real-world data to be more efficient in drug development and commercialization

Keynote Speakers:

Kathleen McGroddy Goetz, Ph.D.
Vice President, Partnerships and Solutions
IBM WATSON HEALTH

Jane Fang
Research and Development Information Head for Clinical Biologics
ASTRAZENECA/ MEDIMMUNE

Featured Speakers:

Ella Nkhoma
Director of Epidemiology
BRISTOL-MYERS SQUIBB

Robert Lubwama, DDS, MPH, Ph.D.
Drug Outcomes Epidemiologist
MERCK

Elizabeth (Betsy) MacLean, PharmD, Ph.D.
Director Global Health and Value/US Outcomes and Evidence – Oncology
PFIZER INC.

Stacy Woeppel
Deputy Director Regulatory Affairs
SANOFI PASTEUR

Important Takeaways:

- ✓ Uncover how IBM Watson uses advanced analytics in combination with real-world data sets to enable predictive analyses
- ✓ Learn how real-world, systems-based innovations can serve as a model to target and engage at-risk populations through the Heart of New Ulm Project
- ✓ Explore Merck's evaluation of whether Hadoop can efficiently and inexpensively meet the storage, retrieval and analysis requirements of big data's immense and variably structured data
- ✓ Discuss how the FDA and industry can collaborate on defining real-world evidence
- ✓ Identify strategies for optimal regulatory interactions and regional differences in approaching real-world studies

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2017

Real-World Evidence Forum

Dear Colleague,

Proving the safety and effectiveness of a drug or device through a randomized clinical trial no longer secures success and profitability after the product is released to the market. It's now necessary for companies to demonstrate evidence of successful real-world outcomes to distinguish their products in an aggressive environment. There are many challenges when integrating real-world evidence into today's drug development process. Operationalizing the process of collecting real-world data, utilizing electronic data sources and understanding regulatory requirements are all issues that need to be better understood within the industry.

ExL Events is excited to announce our first **Real-World Evidence Forum**. Over the course of two days, attendees will learn about data collection, new technologies, trial design, regulatory decision-making, data partners, global standardization and much more. An intelligent lineup of industry professionals will discuss the challenges surrounding real-world evidence. Our attendees will learn to improve their understanding of how to operationalize real-world data, which will decrease costs, define innovative outcomes and minimize the number of patients exposed to harmful medications.

I look forward to welcoming you to Philadelphia this summer!

Sincerely,

Megan Heburn

Megan Heburn

VENUE INFORMATION

Sheraton Philadelphia University City Hotel
3549 Chestnut St.
Philadelphia, PA 19104

To make reservations please call 1-888-627-7070 and request the negotiated rate for **ExL's Real-World Evidence and 2017 Trial Protocol Optimization Design Congress Meetings**. You may also make reservations online at http://bit.ly/2ooGqhE. The group rate is available until **June 30, 2017.** Please book your room early as rooms available at this rate are limited.

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WHO SHOULD ATTEND

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

- **Real-World Evidence**
- **Phase IV**
- **Postmarket Surveillance**
- **Late Phase/Post-Approval**
- **Medical Affairs**
- **Data Management**
- **Data Analysis**
- **Project Management**
- **Business Development**
- **Clinical Development**
- **Global Medical Affairs**
- **Observational Research**
- **HEOR/GHEOR**
- **Patient Safety Surveillance**
- **Clinical Trial Design and Management**
- **Data Management Operational Support**
- **Regulatory Affairs**
- **Drug Safety**
- **Patient-Reported Outcomes**

This conference is also of interest to:

- **CRM/Data Management Software Vendors**
- **Clinical Research Organizations**
- **Clinical Trial Management Software Providers**
- **Regulatory Consultants**

SPONSORSHIP AND EXHIBITION 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 Events will work closely with you to customize a package that will suit all of your needs.

Monday, July 17, 2017

Day One

8:00 Registration and Continental Breakfast

9:00 Chairperson's Opening Remarks

Building Real-World Data

9:15 **Develop an Effective Trial Design Utilizing Real-World Evidence**

- Determine the right type of postmarket study to minimize the effects of bias and provide efficient research findings
- Design a clinical trial that includes most real-world patients without compromising the efficacy or increasing potential risks
- Implement flexible pragmatic models to combine the benefits of collecting data from more real-world settings
- Regulate how data should be analyzed, how the results will be combined with other types of evidence and how these decisions will be put into routine practice

Jane Fang, *Research and Development Information Head for Clinical Biologics,* **ASTRAZENECA/MEDIMMUNE**

10:00 **Justifying and Designing Amgen's Real-World Evidence (RWE) Platform**

- Develop a business case to justify an RWE platform to deliver clinical and commercial insights to the enterprise
- Design a secure and scalable platform that supports global data assets for functional and regional needs
- Create processes to standardize real world data assets for rapid insight generation
- Implement self-service analysis tools to enable direct enterprise-wide access

Leslie Addy, *Senior Manager, Information Systems,* **AMGEN**

Jan Lethen, *Director, Biostatistical, Programming,* **AMGEN**

11:00 Networking Break

11:30 **Learn Innovative Methods to Build Real-World Evidence as Your Enterprise Asset**

- Learn from Intercept about how to use real-world data for pipeline and commercialization insights
- Delve into the concept of potential real-world evidence that could emerge from targeted data linkage
- Analyze how to fill the data gap between clinical trials and actual clinical practice in order to improve the quality and delivery of medical care, reducing overall costs

Shailja Dixit, *Global Head, Health Outcomes and Real World Research,* **INTERCEPT PHARMACEUTICALS**

12:15 Lunch

1:15 **Maximize the Value of Real World Evidence (RWE) Through Strategic Planning and Technology Enablement**

- Discuss how business and study objectives should inform an intelligent RWD collection strategy that will drive clinical research efficiency and provide the RWE necessary for payer and regulatory stakeholder requirements
- Discuss the optimal path for evidence development, from needs assessment through generation, and how fit-for-purpose technology solutions can enhance efficiency and elevate the access of RWD driven intelligence for broader enterprise value
- Review the opportunities and challenges that exist in using RWD and technology solutions where clinical practice and clinical research converge, including a comprehensive, best practices approach

Bill Row, MBA, MS, *Divisional Principal, Real World Evidence.* **ICON COMMERCIALISATION & OUTCOMES**

2:00 **Leverage Data and Evidence-Based Interventions to Drive Community Health Improvements**

- Evaluate the use of electronic health record (EHR) data for community diagnosis and surveillance
- Master how to use data to effectively deploy multilevel interventions for population health improvement
- Identify strategies for using EHR data to align key community partners around a common health agenda and empower them as community catalysts
- Discover how evidence-based solutions help improve health on a local level using the Hearts Beat Back: Heart of New Ulm Project as an effective model

Rebecca Lindberg, *Director Population Health and Professional Education,* **MINNEAPOLIS HEART INSTITUTE FOUNDATION**

2:45 **Getting Real-World Answers from Real-World Evidence: Perspectives from the World's Largest Academic Clinical Research Organization**

- Bring together clinical insights and analytic expertise to shape a research question that yields a meaningful answer
- Overcome data challenges from novel and complex data sources, such as clinical trial data, registries, health system databases, cohort studies, EHRs and claims databases
- Move beyond off-the-shelf applications to optimal, tailored statistical methods that allow for meaningful use of EHR and high-dimensional data and risk prediction
- Ensure data outcomes are used to improve patient health by accurately interpreting and integrating findings into clinical practices

David Gee, *Assistant Director, Research Analytics and Data Science,* **DUKE CLINICAL RESEARCH INSTITUTE**

3:30 Networking Break

4:00 **Discuss How Real-World Data Speeds Up Clinical Innovation While Managing Patient Safety**

- Understand why big data is critical for assuring patient safety during clinical development as well as in the postmarketing setting
- Summarize how the use of real-world data can inform clinical strategy during development and in life cycle management
- Discuss how to leverage real-world data to inform portfolio decisions and strategy
- Recognize the importance of early cross-functional engagement in developing a real-world data strategy throughout the product life cycle

Ella Nkhoma, *Director of Epidemiology,* **BRISTOL-MYERS SQUIBB**

Applying Technology

4:45 CASE STUDY **Merck Case Study: Preparing for the Emergence of Big Data Using the Hadoop Initiative**

- Explore Merck's evaluation of Hadoop, an architecture and methodology designed to efficiently and inexpensively meet the storage, retrieval and analysis requirements of big data's immense and variably structured data
- Investigate how a single technology-enabled platform can be tailored to become a data discovery tool used for commercial insights and reporting
- Prepare for the challenges ahead as we face the inevitable prospect of managing and analyzing big data

Robert Lubwama, DDS, MPH, Ph.D., *Drug Outcomes Epidemiologist,* **MERCK**

5:30 Day One Concludes

Tuesday, July 18, 2017

Day Two

8:00 Continental Breakfast

8:45 Chairperson's Recap of Day One

Applying Technology, Continued

9:00 **Utilize Real-World Data to Renovate Healthcare Through the Use of Watson**

- Address how cognitive computing systems and increases in data are changing the industry
- Implement improved payment models
- Identify how the digitization of healthcare can create opportunities for change
- Learn how Watson supports a higher level of personalized care

Kathleen McGroddy Goetz, Ph.D., *Vice President, Partnerships and Solutions,* **IBM WATSON HEALTH**

9:45 **Discover the Potential of Real-World Evidence for Healthcare and Regulatory Decision-Making**

- Walk through the utility of real-world data, from approval to access
- Discuss possible innovative advances in approval policy structures
- Establish how data gathered from healthcare systems can be used to enhance and support regulatory decisions
- Explore how the FDA and industry can collaborate on defining real-world evidence

Elizabeth (Betsy) MacLean, PharmD, Ph.D., *Director Global Health and Value/US Outcomes and Evidence – Oncology,* **PFIZER INC.**

10:30 **Improve Regulatory Clarity and the Use of Real-World Evidence**

- Address the transparency and integrity of collection and analysis of real-world data
- Research how patient-generated data helps guide policy decisions and improve the approval process
- Recognize the challenges of obtaining valid and complete real-world data
- Examine the lack of common data standards, and the need for more effective methods for matching patient data across diverse systems

Stacy Woeppel, *Deputy Director, Regulatory Affairs,* **SANOFI PASTEUR**

11:15 Networking Break

11:45 **Pinpoint Strategies for Optimal Regulatory Interactions and Regional Differences in Approaching Real-World Studies**

- Learn how to face real-world evidence challenges through an operational and regulatory perspective
- Consider opportunities and challenges for generating industrywide standards
- Understand the regulatory frameworks in the US and worldwide
- Demonstrate regulatory and compliance safeguards to minimize risk

Ashwin Rayasam, *Global Clinical Trial Manager,* **DOCS FOR AMGEN, INC.**

12:30 Lunch

1:30 **Panel Discussion: Generate Global Standardization and Data Quality**

PANEL

- Discuss internationally linked data infrastructure between databases and global data standards
- Review how building a database that connects countries would allow interoperability between diverse data sources
- Examine the benefits of linking international data sets and establishing a framework of standards for data analysis using real-world data
- Assess how global harmonization could reduce inefficiencies

2:15 **Demonstrate Value Through Cross-Functional Teams to Enable Increased Real-World Understanding**

- Deliver insights to cross-functional teams to facilitate the use of data in a timely and cost-effective manner
- Efficiently analyze data so regulatory agencies and payers make better-informed decisions
- Uncover ways teams can work together to improve the internal coverage of data knowledge

Jamie Partridge, *Director, Global Scientific Affairs,* **ABBOTT NUTRITION**

3:00 Networking Break

Working with Payers

3:30 **Construct Partnerships of Eco-Networks for Data Sources, Analytics and Clinical Healthcare Services**

- Locate the right partners to support the building and maintenance of real-world evidence
- Discover how to capture and distribute information from partners for internal use
- Anticipate which stakeholders will need what types of information and adjust strong study approaches to those key considerations
- Discuss factors for evaluating a partner's capabilities, processes and quality of work

Jane Fang, *Research and Development Information Head for Clinical Biologics,* **ASTRAZENECA/MEDIMMUNE**

Kyle Flickinger, *Vice President, Clinical and Commercial Markets,* **HEALTHVERITY**

4:15 Conference Concludes

REGISTRATION
to register CLICK HERE or

Call: 201 871 0474
fax: 253 663 7224
email: register@pmaconference.com/
web: http://pmaconference.com/
Mail: POB 2303 Falls Church Va 22042

Registration Fees for Attending ExL's 2017 Real-World Evidence Forum:

EARLY BIRD PRICING — *Register by Friday, June 9, 2017*	$1,895
STANDARD PRICING — *Register after Friday, June 9, 2017*	$2,095
ONSITE PRICING	$2,195

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Questions? Comments?

Do you have a question or comment that you would like to be addressed at this event? Would you like to get involved as a speaker or discussion leader?

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