Pharmacovigilance and Risk Management Strategies Conference

Short Courses: January 22 | Conference: January 23-25 | Mandarin Oriental Washington D.C. | Washington, DC

PROGRAM CHAIRS

Stella C. F. Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc

PROGRAM COMMITTEE

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Senior Director, Global Patient Safety, Medical and Benefit Risk Management
Eli Lilly and Company

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Lead Medical Officer, Pharmacovigilance Strategy
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Michael Richardson, MD, FFPM
International Head GPV&E and EU Qualified Person for Pharmacovigilance
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Annette Stemhagen, DrPH
Senior Vice President, Safety, Epidemiology, Registries and Risk Management
UBC, An Express Scripts Company

|Overview

DIA's *Pharmacovigilance and Risk Management Strategies Conference* is the leading forum for exploring insights into new technologies and innovative methods and how they can be utilized for pharmacovigilance in the broadest sense. The 2017 program will focus on cutting edge innovation across the entire life cycle of biopharmaceutical products – new therapeutic approaches to diseases that change patients' lives, enlightened evolution of regulatory science that speeds needed products to prescribers and patients, and, most importantly, engagement of patients in the product development and regulatory processes.

|Conference Features

- Short Course Offerings on Sunday, January 22
- Special Hot Topic Panels and Debates
- **Round Table Discussion Luncheons**. Share your conference thoughts and takeaways during one of two luncheons with key thought leaders.
- Table Top Exhibits and Numerous Networking Opportunities

| Learning objectives

At the conclusion of this conference, participants should be able to:

- Employ the current regulatory framework for pharmacovigilance in key markets, including the US and EU
- Examine the influence of recent regulatory developments and expectations in Japan, China, and Mexico on safety and pharmacovigilance practice
- Discuss how advanced therapies and technologies may impact pharmacovigilance and risk management
- Discuss how the needs for access to innovative medicines and for safety information can be balanced during the application of new adaptive development pathways
- Describe considerations for appraising the value of data sources outside the spontaneous reporting system for safety and benefit-risk assessments
- Utilize new approaches for presentation of benefit-risk data and communication of risk-benefit messages to health care providers, patients, and consumers

Message from the Program Co-Chairs

On behalf of the Program Committee and the DIA Board of Directors, we are both delighted and honoured to announce DIA's annual conference on drug safety. The *Pharmacovigilance and Risk Management Strategies Conference* promises to be the best instalment yet in this acclaimed annual series. This is the leading forum for exploring insights into new technologies, innovative methods, and how they can be utilized for pharmacovigilance in the broadest sense.

This year's focus is on cutting edge innovation across the entire life cycle of biopharmaceutical products and the role of pharmacovigilance in shaping the future of optimizing these medical interventions. Pharmacovigilance and risk management are key activities that promote an optimal balance of benefit and risk for patients who need access to both existing and novel products. How can these can be conducted in a deliberate, evidence-based environment that has an appropriate level of regulatory oversight, but also encourages reasoned innovation to address unmet medical needs? How do we choose appropriately among potential safety data sources and analytical methodologies? How can we navigate and interpret confounder-laden data? And most importantly, how do we involve all stakeholders, including patients and health care providers, in the optimization of benefit-risk?

There will be numerous opportunities to broaden your horizons abound at this year's conference. Four short courses, ranging from "Pharmacovigilance and Risk Management Planning" to "Pharmacovigilance Inspection Readiness" will be offered on Sunday, January 22. You are invited to participate in one or more of the 16 current topic round tables that will be facilitated by key thought leaders during the main conference luncheons on Monday and Tuesday. When plenaries are not in session, exhibitors will be showcasing their latest products and services in safety and pharmacovigilance. Networking will continue in a social atmosphere at the conference-organized "Dine Arounds" at selected local restaurants.

As Program Co-Chairs, our goal has been to create a vision for the future of pharmacovigilance and to provide excellent scientific sessions to help build our readiness for that future. We welcome your participation and know that you will benefit from the experience.

Sincerely,

William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc.

Stella C. F. Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

|Continuing Education

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for the CEUs indicated below. Type of Activity: Knowledge

Title	UAN	CEUs
Conference: Day 1	0286-0000-17-005-L04-P	0.725
Conference: Day 2	0286-0000-17-006-L04-P	0.45
Conference: Day 3	0286-0000-17-007-L04-P	0.45
Short Course 1: Pharmacovigilance and Risk Management Planning	0286-0000-17-009-L04-P	.6
Short Course 2: Periodic Benefit-Risk Evaluation Report (PBRER)	0286-0000-17-011-L04-P	.6
Short Course 3: FDA Adverse Event Reporting System (FAERS): Individual Case Safety Reports (ICSR) and Data Quality	0286-0000-17-008-L04-P	.325
Short Course 4: FDA Pharmacovigilance Inspection Readiness	0286-0000-17-010-L04-P	.325

ACPE Credit Requests MUST BE SUBMITTED by March 11, 2017

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DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer the up to 2.2 CEUs. Participants must attend the entire conference or short course in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

Title	CEUs
Conference	1.6
Short Course 1: Pharmacovigilance and Risk Management Planning	.6

Short Course #2: Periodic Benefit-Risk Evaluation Report (PBRER)	.6
Short Course #3: FDA Adverse Event Reporting System (FAERS): Individual Case Safety Reports (ICSR) and Data Quality	.325
Short Course #4: FDA Pharmacovigilance Inspection Readiness	.325

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If you would like to receive a statement of credit, you must attend the program(s), sign in at the DIA registration desk each day, and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **February 9, 2017.**

To access My Transcript:

- Visit DIAglobal.org, select "Sign in" and you will be prompted for your user ID and password
- Choose MENU, found in the upper left corner
- Under CONFERENCES select "Continuing Education"
- Select the blue "My Transcript" button followed by "Credit Request" to process your credit request for the course

When using the Attendance Verification Form
If you would like to receive a statement of credit, you must attend the meeting (tutorial, if applicable; sign in at the registration desk), complete the "Verification of Attendance" form located in your meeting folder, turn in your form to the registration desk at the conclusion of the meeting, and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on
February 9, 2017.

DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

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Short Courses | Sunday, January 22

7:30AM-6:00PM Registration

8:30AM-12:00PM **Short Course 3:** FDA Adverse Event Reporting System (FAERS): Individual Case Safety Reports (ICSR) and Data Quality

Instructors

Sanjay Sahoo
Regulatory Science Staff, Office of Surveillance and Epidemiology
CDER, FDA

Sonja Brajovic, MD
Medical Officer, Office of Surveillance and Epidemiology
CDER, FDA

Judy Harrison, MD
Chief Medical Officer
MedDRA MSSO

Remote Panelist

Jo Wyeth, PharmD
Safety Evaluator, Division of Medication Error Prevention and Analysis, Office of Surveillance and Epidemiology
CDER, FDA

This half-day short course will provide an overview and lessons learned regarding the submission of postmarketing individual case safety reports (ICSRs) in electronic format to the FAERS database, both through the "database-to-database" E2B process, and through the Safety Reporting Portal (SRP). We will discuss the structured data fields and quality issues, with an in-depth focus on suspect product information and pre-coded MedDRA terms for adverse events / medication errors. Examples from FAERS coding quality review will be provided in order to illustrate and distinguish coding of medication errors, off label use, intentional misuse and product quality issues.

Learning Objectives

At the conclusion of this short course, participants will be able to:

- Describe electronic case reporting to FAERS
- Understand data quality issues encountered with electronic ICSR submissions
- Explain quality issues related to suspect product identification, using examples

- Discuss data quality issues related to MedDRA coding, using examples

10:00AM-5:00PM **Short Course 1:** Pharmacovigilance and Risk Management Planning

Instructors
William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc.

Stella Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

This full-day short course will focus on basic aspects of the regulatory framework for pharmacovigilance in the context of risk management planning and on the practical aspects of managing biopharmaceutical product risks in the context of benefits and the health care delivery system. The main focus will be on the EU and US situations, but this will be supplemented with experience gained in other selected jurisdictions.

Learning Objectives
At the conclusion of this tutorial, participants should be able to:
- Discuss similarities and differences in risk management planning in the three ICH regions and other selected jurisdictions;
- Describe the differences between important identified risks and important potential risks;
- Outline the basic structure and contents of an EU Risk Management Plan (in the context of a Risk Management System) and a Risk Evaluation and Mitigation Strategy (REMS); and
- Discuss primary and non-routine tools for managing product risks, how the effectiveness of a selected tool is assessed, and points to consider for the modification, revision, or release of a given non-routine intervention.

10:00AM -5:00PM **Short Course 2:** ICH E2C (R2); The Quantum Leap from PSURs to Benefit-Risk Evaluation (PBRERs): Background, Expectations, and Practicalities

Instructors

Valerie E. Simmons, MD
EU QPPV, Global Patient Safety
Eli Lilly and Company Ltd.

Alison Turney, PharmD
Surveillance Business Process Advisor, Global Patient Safety
Eli Lilly and Company

Christina Phan, PharmD
Associate Director, Safety Evaluation and Reporting, Worldwide Safety and Regulatory
Pfizer

The ICH E2C (R2) guideline on Periodic Benefit Risk Evaluation Reports reached Step 4 in November 2012 and, at that time, represented a significant change from the previous "PSUR" (ICH E2C(R1) format. As such, it is a quantum leap forward, for both industry and regulators alike, towards a document incorporating many new concepts including an integrated, critical evaluation of both benefits and risks of a medicinal product. Initially adopted by the EU, ICH E2C(R2) has subsequently been implemented in multiple countries and regions but not always in a consistent fashion, or necessarily with the same interpretation by different regulatory authorities around the world where it was intended to replace existing requirements for post marketing periodic reporting. It is clear that implementation of the revised periodic report format poses challenges for many companies (regardless of size) who are faced with not only implementing the guideline itself, but also dealing with disparate interpretations that have arisen over the years since E2C(R2) was finalized. The instructors for this tutorial draw on experience from both direct involvement in the development of the ICH guideline itself as well as from experts with extensive experience in actual implementation. The short course will cover the background and expectations behind key sections of the guideline, and will provide an in depth interpretation from the perspective of the expert working group that developed the concept. Based on this theoretic basis, the course will then move to more practical aspects of implementation and lessons learned from experience over the last 4 years. This will include the latest thinking and updates from the EU. The intent of this course is to be interactive and to tailor to the needs of the attendees as much as possible. Questionnaires will therefore be sent to all registered attendees to assess expectations based on level of experience as well as any key questions that they wish the instructors to

specifically address with the aim that answers are developed together in a coaching environment.

Learning Objectives
At the conclusion of this short course, participants should be able to:

- Discuss the main principles defined in the ICH E2C(R2) guideline
- Describe the structure and content of the new PBRER
- Explain the regulatory authority expectations of the PBRER
- Recognize how to implement the PBRER to encompass multiple functions
- Discuss and evaluate the practical aspects in the preparation of the PBRER
- Discuss questions that have been specifically raised by attendees and solicited through a pre-course questionnaire

1:30-5:00PM **Short Course 4:** FDA Pharmacovigilance Inspection Readiness

Instructors
Shiferaw Kibriye, PharmD
Medical Quality Assurance. Head of Inspection Management
Pfizer Inc.

LaShanda Long
Supervisor, Office of Scientific Investigations, Office of Compliance
CDER, FDA

Speaker Invited
Office of Regulatory Affairs
FDA

If a government investigator knocks on your door today, would your organization be ready for an inspection of your pharmacovigilance system? This short course will help get you familiar with the FDA inspection process so that an inspection can be effectively hosted and proactively managed. Hear two FDA experts explain the Agency's expectations and common missteps that result in observations. In turn, learn perspectives from an industry veteran on what to do before, during, and after an inspection. Course instructors will share practical and actionable commentary that you can use to improve and sustain your pharmacovigilance quality system. Active dialogue will be encouraged.

Learning objectives
At the conclusion of this short course, participants will be able to:

- Explain the purpose behind pharmacovigilance inspections and their benefit(s)
- Describe the inspection process
- Outline common inspection observations
- Plan and conduct a response to inspection observations
- Interpret messaging in FDA Untitled Letters and Warning Letters

Day One | Monday, January 23

7:30AM-5:30PM Registration

7:30-8:30AM Continental Breakfast and Networking in Exhibit Hall

8:30-8:45AM **Welcome and Opening Remarks**

Program Co-Chairs
William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc.

Stella Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

8:45-10:00AM **Session 1:** Keynote Address: *Innovative Therapies, Processes and the Growing Role for Pharmacovigilance*

Session Co-Chairs
William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc.

Stella Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

Genetic therapy is now a reality, resulting from a decade-long expansion in knowledge about receptors, molecular pathways, and genetics and the technologies needed to harness them. Fulfilling the promise of this and other advanced therapies to provide "the right therapy to the right patient at the right time" presents new challenges to those entrusted with ensuring access while balancing risks and benefits. This talk will

explore the newest therapies, the challenges they pose to regulators, and the growing importance of pharmacovigilance in meeting these challenges.

Keynote Speaker
Hans-Georg Eichler, MD, MSc
Senior Medical Officer
European Medicines Agency, European Union

10:00-10:30AM Refreshment and Networking Break

10:30AM -12:00PM **Session 2:** FDA Updates

Session Chair
Gerald J. Dal Pan, MD, MHS
Director, Office of Surveillance and Epidemiology
CDER, FDA

In this session, FDA representatives will provide updates from the Office of Surveillance and Epidemiology (OSE) within CDER. Topics will include postmarketing safety monitoring within OSE, overview of pharmacoepidemiology, pharmaceutical risk management, medication error prevention, and updates from the Office of Generic Drugs.

Overview and FDA Updates
Gerald J. Dal Pan, MD, MHS
Director, Office of Surveillance and Epidemiology
CDER, FDA

Update from the Office of Generic Drugs
John R. Peters, MD
Deputy Director, Office of Generic Drugs
CDER, FDA

Howard D. Chazin, MD
Medical Officer, Clinical Safety and Surveillance, Office of Generic Drugs
CDER, FDA

Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using EHRs
Christian Hampp, PhD, BS Pharm
Senior Epidemiologist, Office of Surveillance and Epidemiology
CDER, FDA

12:00-1:30PM Luncheon in Exhibit Hall
Round Table Luncheon Discussions

There will be a 30 minute session for a limited number of participants to join round table discussions during the lunch break. Key thought leaders will help facilitate the discussions.

1:30-3:00PM **Session 3:** Changing Environments

Session Chair
E. Stewart Geary, MD
Chief Medical Officer, Senior Vice President
Eisai Co., Ltd., Tokyo, Japan

Both mature and developing pharmaceutical markets continue to go through changes in regulations or expectations for conduct of pharmacovigilance. This session will present recent developments in Japan, China and Mexico, which are each either undergoing changes in regulations or expectations related to postmarketing pharmacovigilance and the practice of drug safety during clinical development.

Recent Issues with Pharmacovigilance Regulatory Compliance in Japan
E. Stewart Geary, MD
Chief Medical Officer, Senior Vice President
Eisai Co., Ltd., Tokyo, Japan

Safety Aspects for An Innovative Product in Local Clinical Trials in China: The Transition Through Registration and Postmarketing Challenges
Gao Gao, MD
Director and Global Safety Risk Lead, Safety Surveillance and Risk Management
Pfizer (China) R&D Co., Ltd.

Challenges with Recent Post-market Requirements in Mexico
Sajjan Daniel, MD
Vice President, Global Head of Safety Surveillance, Global Drug Safety
Shire

3:00-3:30PM Refreshment and Networking Break

3:30-5:00 PM **Session 4:** Safety Data rEvolution

Session Chair
Stephen Knowles, MD, MRCP
Senior Director, Global Patient Safety
Eli Lilly and Company

The spontaneous reporting system (SRS) has been a key tool for monitoring post-marketing product safety since the thalidomide tragedy in the 1960s. Today, however, we are in the midst of a safety data rEvolution, and pharmacovigilanties have an insatiable appetite for meaningful data from sources beyond the SRS, particularly digital data. So, the data feast is on and not likely to stop, but the practical conversion of bytes to insights must be refined. Further, more work is needed to confirm the enduring value of such data for safety and benefit-risk assessments. This session will explore the current status of FDA's Sentinel program, Real World Evidence and registry data, and practical aspects of screening incidental safety information from Customer Engagement programs.

The Sentinel Active Surveillance Program: What Is the Direction of Travel?
Aaron L. Niman, MPH
Research Officer, Office of Surveillance and Epidemiology
CDER, FDA

How Can Registries and Real World Evidence Better Complement Interventional Clinical Trials?
Andres Gomez, PhD
Vice President, Head of Epidemiology, Safety Science and Analytics
Bristol-Myers Squibb

Automation of Case Processing and Analytics - AI Application in Pharmacovigilance
Juergen Schmider, MD, PhD
Vice President, Pharmacovigilance & Safety Evaluation and Reporting
Pfizer Inc.

5:00-5:15 PM Stretch Break

5:15-6:45PM **Session 5:** Integrated Adaptive Development and Decision Making

Session Chair
Stella C. F. Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

For patients with serious illnesses and unmet medical need, access to innovative medicines as early as possible is important. Randomised controlled clinical trials are important for establishing efficacy of a medicine but may provide only limited evidence of how a medicine will perform in the real world. There is relatively little known about the true

safety profile of a drug at the time of "normal" authorisation and some critics' voice concerns about patient safety as an argument against regulatory pathways providing earlier access. Some stakeholders are wanting evidence of effectiveness before making new medicines available for patients. How do we balance all these conflicting needs and how to we plan a development pathway to satisfy all, or at least most, stakeholders?

EMA Adaptive Pathways Pilot: What We've Learned and Future Direction
Hans-Georg Eichler, MD, MSc
Senior Medical Officer
European Medicines Agency, European Union

Adaptive Biomedical Innovation: The Way Forward
Gigi Hirsch, MD
Executive Director
Massachusetts Institute of Technology (MIT) Center for Biomedical Innovation

Adapt Smart and GetReal: Where We Are and Where We Are Going
Sarah Garner, PhD
Associate Director – Science Policy and Research
National Institute for Health and Care Excellence (NICE)

Day Two | Tuesday, January 24

7:30AM-5:00PM Registration

7:30 -8:30AM Continental Breakfast and Networking in Exhibit Hall

8:30 -8:45AM **Welcome and Opening Remarks**

Program Chair
William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc.

8:45-10:15AM **Session 6:** EU Regulatory Updates

Session Co-Chairs
Mick Foy
Group Manager, Vigilance Intelligence and Research Group
MHRA

Stephen Knowles, MD, MRCP
Senior Director, Global Patient Safety
Eli Lilly and Company

This session will provide an update on the current state of EU pharmacovigilance regulations, bringing in EMA, Industry, and patient perspectives.

In particular, the discussions will focus on the findings and recent trainings of the SCOPE (Strengthening Collaboration for Operating Pharmacovigilance in Europe) Joint Action, a three-year project to help medicines regulators operate pharmacovigilance systems according to the EU legislative requirements. Latest updates on the Good Pharmacovigilance Practices (GVP) measures will include the new chapter on Biological medicinal products and status of the new Module VI on Management and reporting of adverse reactions to medicinal products.

"Has the EU pharmacovigilance legislation translated to better safety outcomes for patients?" A special panel of patient, industry, academic, and regulatory stakeholders will examine the implementation of the 2012 legislation and whether there has been a measurable impact on patient safety. The audience will be invited to join in an interactive Q&A in the latter part of this session.

Status of the EU Pharmacovigilance Regulations (From IDMP to RMP)
Mick Foy
Group Manager, Vigilance Intelligence and Research Group
MHRA

Has the EU Pharmacovigilance Legislation Had a Positive Impact on Patient Safety Outcomes?

Panelists

Vicki Edwards
QPPV and Head of Affiliate Vigilance Excellence
AbbVie Ltd.

Valerie Simmons
QPPV
Eli Lilly and Company Ltd.

Mick Foy
Group Manager, Vigilance Intelligence and Research Group
MHRA

Saad Shakir, MD
Director
Drug Safety Research Unit

Panelists Invited

10:15-11:00AM Refreshment Break and Networking in Exhibit Hall

11:00AM-12:00PM **Session 7:** Globalization of the Responsible Person

Session Chair
William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc.

A systematic approach to quality is essential to meet legal obligations for monitoring medical product safety and for protecting patient safety. To facilitate oversight of this requirement and to ensure that a marketing authorization holder (MAH) meets its legal obligations for monitoring the safety of its products, the EU first defined the requirement for a responsible person, termed a Qualified Person for Pharmacovigilance (EU QPPV) in Directive 2001/83/EC (Art 104). Over time, other regulatory jurisdictions have extended this concept, i.e., an individual person who serves as the single focal point with responsibility for oversight of various aspects of the structure, performance, and maintenance of the MAH's local, regional or global pharmacovigilance system. The title of the role differs across regions as do its responsibilities and legal obligations; this non-harmonized approach requires a thoughtful approach to managing the relevant global requirements. This session provides a high-level snapshot of the changing global landscape, followed by a panel discussion with perspectives on pragmatic approaches for efficient organizational and operational solutions as the role of the responsible person evolves.

The Changing Landscape and New Regional Requirements for Responsible Persons for Pharmacovigilance
William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc.

How are Companies Addressing the Changing Requirements for the Responsible Person?

Panelists
Mariette Boerstoel-Streefland, MD, MBA, MS
Senior Vice President, Head Global Drug Safety
Shire

Michael Richardson, MD, FFPM
International Head GPV&E and EU Qualified Person for Pharmacovigilance
Bristol-Myers Squibb

Speaker Invited
Eli Lilly and Company Ltd

Speaker Invited
AbbVie Ltd

12:00-1:30PM Luncheon in Exhibit Hall

Round Table Lunch Discussions
There will be a 30 minute session for a limited number of participants to join roundtable discussions during the lunch break. Key thought leaders will help facilitate the discussions.

1:30-3:00PM **Session 8:** Advances in Benefit-Risk

Session Chair
Elizabeth E. Garrard, PharmD
Executive Vice President, Global Safety Operations
Clinipace Worldwide

Benefit risk evaluation is key to decision-making for most stakeholders involved with innovative medicines. Whereas regulators evaluate it at a population based level, healthcare professionals and patients need to understand how it affects them at the individual level: "Is drug A the right treatment for me/my patient?" This session will explore different measures for looking at benefit risk and new ways in which the data can be visualized to facilitate decision making. A system which helps integrate evidence across different data sources for signal analysis will be demonstrated.

Overview of Benefit-Risk Assessment in Medical Product Development: Context for Patient Engagement
Tarek Hammad, MD, PhD, MS, MSc, FISPE
Executive Director, Pharmacoepidemology
Merck Research Laboratories

Presenting and Communicating Benefits and Risks for Medical Decision-Making: Innovative Visualization Methods
Lesley Wise, PhD
Managing Director, Wise Pharmacovigilance and Risk Management Ltd
London, United Kingdom

Integrating Evidence Across Multiple Data Sources for Signal Analysis: A Demonstration
Mick Foy
Group Manager, Vigilance Intelligence and Research Group
MHRA

3:00-3:30PM Refreshment and Networking Break in Exhibit Hall

3:30-5:00PM **Session 9:** Engaging the Customer: Health Care Providers

Session Chair
Michael Richardson, MD, FFPM
International Head GPV&E and EU Qualified Person for Pharmacovigilance
Bristol-Myers Squibb

New data sources and methodologies are improving our ability to assess risk and risk-benefit balance associated with medical product use, but this information must be appropriately shared to facilitate decision making by all stakeholders, including health care providers and especially patients. How are risk and risk mitigation approaches most effectively shared with health care providers, and how can effective feedback on adverse events be best communicated to sponsors? What approaches to sharing benefit-risk information are most meaningful and useful to the patient in his or her decision making? What tools does FDA use to communicate with the public about drug safety and risks, and what impact have these messages had on health care professional and patient or consumer decision making? In this session, patient representatives and communication professionals from industry and FDA will explore how well current methods are working and how they can be improved.

Effective Risk Management Communications with Health Care Providers
Reema Mehta, PharmD, MPH
Head of Risk Management Center of Excellence
Pfizer

Patient Perspectives on Risk-Benefit and Risk Management Messages
James A Seaton
Owner and Executive Consultant, Seaton Associates
PatientsLikeMe Team of Advisors 2016-2017

FDA Risk Communications to the Public: Impact and Outcomes
Paula Rausch, PhD
Director, Division of Health Communications
Office of Communications
CDER, FDA

Sally Okun
Vice President, Advocacy, Policy, and Patient Safety
PatientsLikeMe

5:00-6:00PM Networking Reception in the Exhibit Hall

Day Three | Wednesday, January 25

7:15 AM-3:00PM Registration

7:15-8:15AM Continental Breakfast in Exhibit Hall

8:15-8:30AM **Welcome and Opening Remarks**

Program Co-Chair
Stella C. F. Blackburn, MD
Vice President, Global Head of Risk Management
Quintiles Inc.

8:30-10:00AM **Session 10:** Advanced Therapies

Session Co-Chairs
Mariette Boerstoel-Streefland, MD, MBA, MS
Senior Vice President, Head Global Drug Safety
Shire

Robert L. Levin, MD
Director, Division of Pharmacovigilance-I, Office of Surveillance and Epidemiology
CDER, FDA

In recent years we have seen fascinating new approaches to treatment options. Instead of supplementing deficiencies, or chemically interfering in dysfunctioning bodily functions, new technologies are being developed and explored that go beyond repeated administration of a product with a relatively predictable mechanism of action. We are now starting to see technologies developed to tackle the disorder more at the core, and even

potentially repair it. Examples are gene therapy, mRNA interference, stem cell therapy and regenerative medicines.

Such novel approaches pose an interesting challenge for safety monitoring; there are many unknowns and concerns about what such manipulations of the human body may evoke, and what off target effects one can expect. E.g. carcinogenicity (esp. gene therapy), and long term effects are a big concern.

This session will educate us on some of these new treatment approaches, and discuss considerations for patient safety.

Pharmacovigilance and Risk Management of Advanced Therapies
Dina Tresnan, DVM, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Pharmaceuticals

Precision Medicine, Pharmacovigilance, and Risk Management
Gerald L. Messerschmidt, M.D., FACP
Chief Medical Officer
Precision for Oncology

Safety Considerations for Regenerative Medicine
Abla Creasey, PhD
Associate Director - Therapeutics
California Institute of Regenerative Medicine

10:00-10:30AM Refreshment and Networking Break in Exhibit Hall

10:30 - 12:00 PM **Session 11:** Advanced Technologies

Session Chair
William W. Gregory, PhD
Senior Director, Worldwide Safety and Regulatory
Pfizer Inc.

The use of advanced technologies in the management of chronic diseases is increasing. For example, the use of mobile apps to aid the control of diabetes and the use of wearable technologies to monitor patients health. These technologies are designed to analyze large amounts of data and enable more real time decision-making for patients and their physicians. One example where these technologies are being increasingly used is in the management of diabetes. It is now possible for a patient's blood glucose to be continually monitored, with the results being

analyzed in the cloud and then the patient's insulin pump being instructed on changes in the insulin infusion rate. Other technologies utilize the cloud to advise patients on bolus insulin doses. These exciting advances, of course, pose questions such as cyber security, who 'owns' the data in the cloud, as well as questions for patients, regulators and pharmacovigilance departments – what are the benefits and risks, what are the requirements regarding the collection of AEs, can the data in the cloud be used for signal detection? This session will bring together experts from the scientific and pharmacovigilance fields and patient perspectives to discuss these questions in relation to the management of diabetes.

State of the Technology and Devices Used in Diabetes Management
Howard Wolpert, MD
Distinguished Medical Fellow-Innovation, Delivery and Device
Eli Lilly and Company

Patient Perspectives on Benefits, Risks, and Safety Measures
Campbell Hutton, MSPH
Senior Director, Regulatory Affairs – Devices
JDRF

Implications and Challenges for Pharmacovigilance
Murray Malin, MD
Medical Director, Medical Safety Evaluation, Pharmacovigilance and Patient Safety
AbbVie

12:00-1:30PM Luncheon and Networking in Exhibit Hall

1:30-3:00PM **Session 12:** Hot Topic Panel

Session Co-Chairs
Lisa Melanie Harinstein, PharmD, BCPS
Safety Evaluator, Division of Pharmacovigilance I, Office of Surveillance and Epidemiology
CDER, FDA

Annette Stemhagen, DrPH
Senior Vice President, Safety, Epidemiology, Registries and Risk Management
UBC, An Express Scripts Company

The FDA IND Rule on Safety Reporting is a topic that is continuously evolving. This session will highlight issues such as: How to understand,

develop, and implement an anticipated events review process? How does the guidance apply to complex safety reporting situations? How to manage compliance in multiple regions? In this session, regulatory and industry representatives will present different perspectives on these issues and engage with the audience in open discussion.

FDA's IND Safety Reporting Rule: Implementation and Impact
Jonathan P. Jarow, MD
Senior Medical Advisor to the Center Director
CDER, FDA

The *Advancing IND Safety Reporting Project* of the Clinical Trials Transformation Initiative
Marsha Millikan
Advisor, Expedited Reporting Global Patient Safety
Eli Lilly and Company

Advancing IND Safety Reporting Project of the Clinical Trials Transformation Initiative

A Global Perspective on IND Safety Reporting
Leann Fieldstad, PharmD
Vice President, Global Pharmacovigilance Operations
Parexel International

Panel Discussion
(All Presenters)

3:00-3:15PM **Closing Remarks**

3:15PM **Conference Adjourned**