INSIDER UPDATE

Pharmacovigilance and Risk Management Strategies 2014

Tutorials: January 12 | Meeting: January 13-15

Renaissance Washington DC Downtown Hotel | Washington, DC

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Insider Update

This edition of *Insider Update* provides insights from key thought leaders from industry and regulatory agencies about what you can expect on the current issues and associated challenges impacting drug safety throughout all phases of development and marketed use.

All of the experts we interviewed will be presenting at Pharmacovigilance and Risk Management Strategies 2014.

"More patient engagement expansion is a welcomed and hopeful sign."

"It is essential that patients have the opportunity to provide input to product and policy decisions made by the FDA."

"Leveraging social media information in a proactive pharmacovigilance strategy may unlock its potential as a value-add in this space."

Are YOU Ready to Get the Insider Scoop?

#1

John Brownstein, PhD

Manager and Associate Professor
Boston Children's Hospital and Harvard Medical School

Q: What are some novel methods for safety surveillance and what are some of the benefits?

A: "Over the past 20 years, Internet technology has significantly changed the landscape of public health surveillance and epidemic intelligence gathering. Disease and outbreak data is disseminated not only through formal online announcements by government agencies, but also through informal channels such as social networking sites, blogs, chat rooms, web searches, local news media, and crowdsourcing platforms.

Informal data streams have been credited with decreasing the time between an outbreak and formal recognition of an outbreak, allowing for an expedited response to the public health threat. Collectively, these online sources create an image of global public health that is fundamentally different from the one produced by traditional public health surveillance infrastructure.

The advent of openly available news aggregators and visualization tools has spawned a new generation of disease-surveillance 'mashups' (Web application hybrids) that can mine, categorize, filter, and visualize online intelligence about epidemics in real time.

For instance, Health-Map is an openly available public health intelligence system that uses data from disparate sources to produce a global view of ongoing infectious disease threats. It has between 1,000 and 150,000 users per day, including public health officials, clinicians, and international travelers. Other similar systems include MediSys, Argus, EpiSPIDER, BioCaster, and the Wildlife Disease Information.

The same methods for infectious disease surveillance are being applied to drug safety surveillance. From our work, we have been able to ascertain thousands of self-reports of patient experience with pharmaceutical products. The hope is that these data will provide a new window into product safety and enable timely situational awareness."

#2 Q: What is the role of patients in risk management and drug safety?

Marc Boutin, JD

Executive Vice President & Chief Operating Officer
National Health Council (NHC)

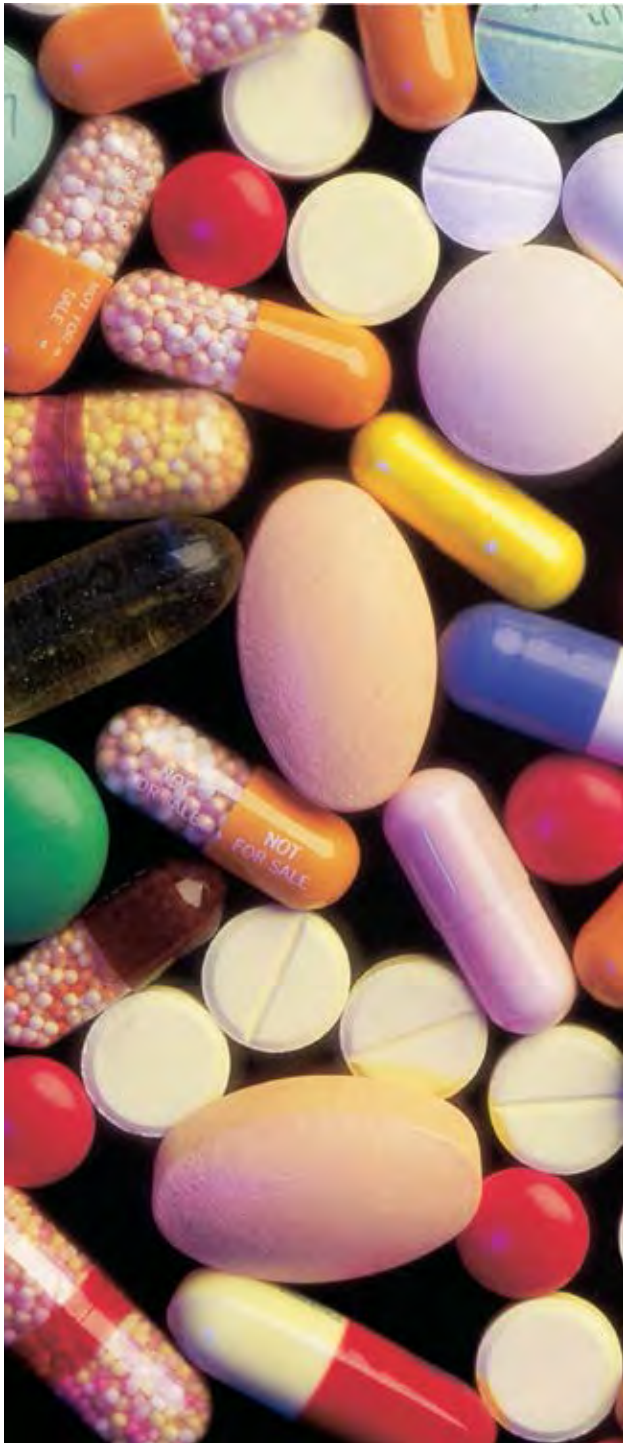
A: "The National Health Council is deeply committed to promoting the development of new treatments that could enable people living with chronic diseases or disabilities to live longer, healthier, and more robust lives. For decades, people with chronic conditions have strongly advocated for ways to incorporate their views on how much risk they are willing to tolerate, especially for diseases that aren't yet treatable. Too often the judgments made in the research and regulatory arenas about the benefits and risks of treatment options appear to be made from the perspective of people who are generally healthy, rather than those who would likely take the medicine.

We are now seeing a heightened awareness of the need to incorporate the patient voice throughout the development and regulatory processes. This more expansive patient engagement is a welcomed and hopeful sign. However, we need to develop agreed-upon standards for methods of conducting patient engagement in drug development. These standards will have the potential to strengthen the processes for incorporating patient-identified outcomes, designing Phase III clinical trials, and increasing predictability in the regulatory review process. The end result will be high-value medicines that are widely covered, appropriately reimbursed, and used by patients."

Diane D. Edquist Dorman

Vice President, Public Policy
National Organization For Rare Disorders (NORD)

A: "It is essential that patients have the opportunity to provide input to product and policy decisions made by the FDA, particularly with regarded to risk tolerance associated with the use of specific products. There are mechanisms in place within the agency, but the input does not necessarily occur at the time that risk tolerance and other critical issues are being deliberated, and does not necessarily represent a broad spectrum of patient views. At any point — from pre-IND and beyond — patient contributions would be of value to FDA decision-makers."



#3

Peg Fletcher, MD, PhD

President
MedAssessment Inc.

Q: Have we given patients the tools they need to take an active role in risk management and drug safety?

A: "Patient input to public policy and the Risk Management Plan (RMP) for an individual product currently comes from two main sources: patient advocacy groups, and individual patients who report their experiences after taking a medicine, whether in a clinical trial or after approval. Physicians and experts in public policy may not recognize the full breadth of cultural and individual variation in assessing personal risk.

Patients need a way to communicate how they value 'benefits' and 'risks.' Benefit-risk policy decisions focused more on survival than the total 'AUC of Suffering' may not reflect the decisions individual patients would make. Health care professionals and regulatory authorities are best able to assess the accuracy of data about 'benefit' and 'risk,' but patients (or their families), when informed, are best able to decide which 'benefits' or 'risks' are important to them individually. We have the responsibility to make information understandable, to provide improved tools for patients to communicate their views, and create tools that will capture the full range of risks."

#4

Paula Taborelli

Regional Director Pharmacovigilance, Europe and Latin America
Global Pharmacovigilance & Epidemiology
Bristol-Myers Squibb, Agentina

Q: What are some of the key regulatory challenges toward Risk Management Plans (RMPs) in Latin America?

A: "RMPs have already started to take a significant place in the agenda of regulators and the pharmaceutical industry in this geography. Although the local legislation regarding pharmacovigilance as a whole, and RMPs in particular, is in different degrees of evolution in the Latin American countries, a strong development can already be seen in countries like Brazil, Argentina, and Mexico.

The regulators in Mexico have a growing interest on the local additional risk-minimization activities that the pharmaceutical industry may be required to implement; Brazil is looking very closely at EMA's requirements for new MA authorized in the EEA; and Argentina is requesting RMPs for any new product filing and new indications. Many other countries in this geography are following a similar path, with increasing risk management requirements in Venezuela, Peru, and Chile, to name a few. This means that RMPs cannot be conceived from a strategic, tactic, and regulatory point of view as unique to some regions (US and EU).

A true global approach is now required, and many health authorities in Latin America are mandating RMP to grant and/or maintain authorizations for new products and/or indications.

Having a global risk management strategy, which enables pharmaceutical companies to have a clear global position of what additional actions are needed for that product to minimize risks at a global level, is the first step in the right direction. A good dialogue with regulators and referents from the local health care system is necessary to gain a better understanding of each local country-specific requirements and achieve successful implementation."

#5

Linda J. Scarazzini, MD

Head, Medical Safety Evaluation
AbbVie

Q: What is the role of social media in providing better information, improving outcomes, and effective management of drug safety operations?

A: "Social media has the potential to advance health literacy, safety, and transparency in the pharmaceutical industry, although potential pitfalls and liabilities have inhibited the industry's participation. In spite of these challenges and fears, there are compelling facts that social media matters. Eight in ten internet users look online for health information, making it the third most popular online activity among those included in a recent Pew Internet Project survey. Patients drive online discussions. This digitization of health care by pharmaceutical companies is slow as FDA has yet to issue its long-awaited guidance on the use of social media. However, leveraging social media information in a proactive pharmacovigilance strategy may unlock its potential as a value-add in this space."

#6

Mariette Boerstoel-Streefland, MD, MBA, MS (epi)

Chief Safety Officer, Vice President Global Drug Safety and Medical Information & Communication
Forest Research Institute

Q: What role does real-world evidence (RWE) have in drug safety?

A: "Electronic medical records can provide crucial information about patients' experiences with their diseases and treatments and provide additional insights about efficacy and safety of drugs outside of the controlled study environments.

The relatively recent and growing availability of large datasets of drug use in real-life settings is providing a great additional tool for pharmacovigilance. Whereas historically, safety professionals have had the difficult task of teasing out 'evidence' on safety profiles and risks from limited and restricted datasets of clinical trials, and the very crude and random info gathered from spontaneous reports, there is now this extra and rich source of information.

RWE data can be especially useful to further study potential signals identified in clinical studies and spontaneous reports, or suspected based on mechanism of action, experience with same drugs in class, etc. It is most suitable for rare outcomes, or for safety signals that may overlap with underlying disease symptoms. There are obvious limitations to this source of data, and it is very important to be aware of those before diving into the abundance of patient records out there.

While there have always been some common areas between the fields of pharmacovigilance and pharmacoepidemiology, over the past few years we have seen a significant convergence."

#7

JP Clement, MD

Vice President Drug Safety and Pharmacovigilance
Onyx Pharmaceuticals, Inc.

You're invited to this global three-day annual meeting on Pharmacovigilance and Risk Management Strategies:

Are YOU Eager to Know More?

- What are the new and updated legislation in various ICH regions?
- What is the current regulatory framework for pharmacovigilance in global regions?
- What are the operational challenges of implementing global Benefit-risk analyses and risk management plans?
- How are new information technologies and social media impacting pharmacovigilance?
- What role does epidemiology play in safety analysis?

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Your Special Invitation to the Annual Meeting You Cannot Afford to Miss!

We would like to invite you to this year's Pharmacovigilance and Risk Management Strategies 2014, being held **January 12-15** in **Washington, DC**, where you'll get the answers to all your questions.

Session Topics:
- **FDA Updates**
- **EU Regulations – Regulatory Overview**
- **Drug Safety in China**
- **Harmonization**
- **Real World Evidence**
- **Social Media**
- **Benefit-Risk and Risk Management Patient Perspective**
- **Patient Perspective**

Sunday, January 12 Tutorial Topics:

Pharmacovigilance and Risk Management Planning
Instructor: William W. Gregory, PhD
Senior Director, Safety and Risk Management, Pfizer Inc.

Introduction to Pharmacoepidemiology and Applications in Premarketing and Postmarketing Surveillance, Risk Management, and Value Demonstration
Instructor: Annette Stemhagen, DrPH, FISPE
Senior Vice President, Safety, Epidemiology, Registries and Risk Management
United BioSource Corporation

ICH E2C (R2); The Quantum Leap from PSURs to Benefit-Risk Evaluation (PBRERs)
Instructor: Valerie E. Simmons, MD, FFPM
EU QPPV, Global Patient Safety, Eli Lilly and Company Limited, UK

Pharmacovigilance System Master File
Instructor: Noha Kassem, PhD
Senior Director of Quality in Global Patient Safety, Eli Lilly & Company Ltd., United Kingdom

Meeting Highlights:

Networking & Exhibits
- Networking Reception: Monday, January 13
- Tabletop Exhibits: January 13-14

Who Should Attend?
Intermediate to Advanced Clinical Safety Professionals who are involved in:

- Pharmacovigilance/Drug Safety
- Medical Product Safety Assessment
- Clinical Research
- Pharmacoepidemiology
- Health Outcomes
- Risk Management
- Regulatory Affairs
- Data Analysis
- Medical Information

It is also designed for professionals who work for:
- Industry: Pharmaceuticals and Biologics
- Academic Research Centers
- Clinical Research Organizations
- Regulatory Agencies

Interested in Exhibiting?
Get the word out about your organization. Submit your application to exhibits@diahome.org today!

We look forward to seeing you in Washington, DC!

REGISTER ONLINE

You Might Also be Interested in:

Meetings:

- Benefit-Risk Assessment from Inception to Maturation: Aligning Regulatory and Industry Goals
  February 10-11 | Bethesda, MD | *Register by January 21 to Save!*
- Medical and Scientific Communications 2014 Annual Forum
  March 9-12 | Orlando, FL | *Register by February 17 to Save!*

Training Courses:

- Risk Management and Safety Communications
  March 3-4 | Horsham, PA | *Register by February 11 to Save!*
- CRO - Clinical Vendor Oversight: Vendor Life Cycle Management for Quality and Performance
  March 24-25 | Horsham, PA | *Register by February 26 to Save!*
- Introduction to Signal Detection and Data Mining
  April 1 | Horsham, PA | *Register by March 11 to Save!*
- Pragmatic Approaches to Drug Safety Across the Premarketing and Postmarketing Continuum
  April 2-4 | Horsham, PA | *Register byMarch 12 to Save!*

Online Learning Course Archive:

- Project Risk Management: Dealing with the Certainty of Uncertainty

Archived Webinars:

- Safety and Social Media: Is this the Question or the Answer?
- Risk Management of Medicinal Products: REMS and RMP - Need for Harmonization Within the ICH Region?
- Two-part Webinar Series: Impact of the New European Pharmacovigilance Legislation and Important Updates
- Eight-part Archived Webinar Series: Assessing the Benefits and Risks of Medicines

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