Virtual Workshop
Innovative Approaches to Drug Safety

COST OF ADVERSE EVENTS

The cost of Adverse Drug Reactions and Adverse Drug Events is estimated at $3.5 billion a year but suspected to be $25 billion a year if unreported ADRs are considered. Consequences include an increased cost for treatment, increased length of hospital stay, higher readmission rates and higher in-hospital mortality.

COST OF DRUG SAFETY

By 2025, the outsourced pharmacovigilance market will be worth about $10.27 billion with an expected growth of 13.1% CAGR. Main drivers to this growth are regulatory requirements and increasing incidence of Adverse drug events due to an aging population and increasing demand for treatment for chronic diseases.

VISION FOR THE FUTURE

Pharmacovigilance needs reform to evolve beyond compliance in order to produce better quality, actionable intelligence that is responsive to the needs of stakeholders within the healthcare ecosystem, including healthcare providers and patients.

Date	**15 November 2019**
Time	**1 to 5 PM EST**
Venue	Online
Cost	Free
Registration	https://www.engagez.net/node/216946?

The current practice of pharmacovigilance is fraught with challenges and limitations. Still, new technologies, perspectives, and concerns are shaping the way stakeholders will need to conduct this crucial activity in the coming years. You are cordially invited to join our workshop on the future of pharmacovigilance. We offer you an opportunity to participate in a robust, informative, and professional discussion about the future of pharmacovigilance. We seek your perspectives on the issues before us today and how they will influence the drug safety environment in the 2020s.

We understand the challenges and limitations of the current ways to conduct the business of pharmacovigilance and seek your perspective to achieve broader consensus. Topics of interest include the role of stakeholders in shaping the informational needs, system responsiveness, production of real-world evidence, incentives and barriers to investment into automation and AI tools, the monetary value of safety information, patient privacy issues, and innovative approaches toward generating evidence.

TOPICS

- Stakeholders' information requirements
- Benefit:risk profile assessment
- Nature of evidence in PV
- Real-world data / real-world evidence
- AI, machine learning, automation
- Financial impact of ADEs
- Monetary value of safety information
- Patient privacy
- Incentives and barriers to investment

Veracuity performs collection and processing of adverse drug events of pharmaceutical products, biologics, nutraceuticals and medical devices originating in the context of medical care and during clinical trials. We do this for and on behalf of concerned stakeholders such as manufacturers and healthcare providers to support them in their reporting obligations and to facilitate their insight into their own operations. The ultimate aim is to decrease liabilities resulting from preventable patient harm through the analysis of patterns of use.

"Accurate and timely insight into the true performance of pharmaceutical products in the clinical context is an essential prerequisite needed to reduce liability associated with avoidable patient harm."

Jonathan M Fishbein, MD

The unbearable cost of pharmacovigilance

Despite significant investment, drug safety surveillance systems produce minimum actionable information

The visibility of Adverse Drug Events (ADEs) data for physicians is insufficient, making it difficult for them to adjust their prescribing practices, perpetuating the occurrence of preventable error-related injuries and their associated liability risks.

Adverse Drug Events are the largest single category of adverse events in hospitalized patients responsible for 19% of all injuries. An estimated 380,000 to 450,000 preventable Adverse Drug Events occur annually in U.S. hospitals. The incremental cost of an Adverse Drug Events was estimated to be $5857 22 years ago (Bates, 1997) and is undoubtedly higher today. This places the estimated cost of Adverse Drug Events at $3.5 billion a year and $25 billion a year if unreported Adverse Drug Events are considered. In inpatient settings, Adverse Drug Events account for 1 in 3 of all hospital AEs, affect about 2 million hospital stays a year, and prolong hospital stays by 1.7 to 4.6 days.

In outpatient settings, Adverse Drug Events account for over 3.5 million physician office visits and 1 million emergency department visits a year and approximately 125,000 hospital admissions a year. High-priority targets defined by the National Action Plan include bleeding caused by anticoagulants, hypoglycemia associated with diabetes agents, and opioid overdose. The financial burden of pharmacovigilance activities has been steadily increasing over the last decade. The main drivers include more stringent regulatory requirements, increasing incidence and prevalence of adverse drug reactions due to demographic changes and liability resulting from high-profile product failures. Yet, other stakeholders in the healthcare ecosystem such as physicians, pharmacists, hospital administrators and patients remain underappreciated and underserved by current pharmacovigilance practice.

VERACUITY, LLC
https://veracuity.com/

ARETE-ZOE, LLC
https://aretezoe.com/

WORKSHOP PROGRAM

Jonathan M Fishbein, MD
Founder and President, Veracuity LLC

Jonathan M Fishbein, MD, is a surgeon and transplant immunologist by training, Dr. Fishbein is the co-Founder and President of Veracuity, LLC. He has held various leadership positions at leading contract research organizations for most of his 30+ year career, most recently Sr. Vice President for Safety and Commercialization at PRA Health Sciences. He was the first Director of the Office for Policy in Clinical Research Operations at the NIAID Division of AIDS from 2003 - 2005. Dr. Fishbein also serves as Executive Director for Kavana Health, a firm dedicated to phytocannabinoid research and wellness.

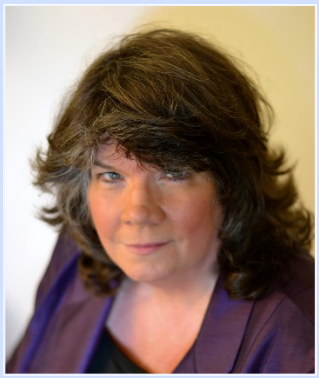
Pharmacovigilance Must Grow Up
Pharmacovigilance needs to catch up to the information age, deploy new capabilities and utilize technology that will improve the safety of all therapeutic products.

Matthew D Whalen, PhD
Alliance for Clinical Research Excellence and Safety

Dr. Whalen is the founding Chief Operating Officer (COO) of the neutral non-profit global Alliance for Clinical Research Excellence and Safety (ACRES). In his career, Whalen has worked in and with Government, Industry, Academia, Non-Profit and Multi-Lateral organizations supporting strategic and organizational change including in biomedical clinical research. He is a social entrepreneur investing time and expertise in organizations and programs that are socially-responsible. He has also served on Boards and leadership committees of organizations including professional societies and journal editorial Boards. Whalen's University faculty roles include Business and Public Policy, Interdisciplinary Honors, as well as various Arts and Humanities at the University of Maryland, College Park and Temple University, Philadelphia, PA.

Independent Investigation for Biomedical R&D Product Safety Crises
Based on the current state of biomedical R&D's pain and pressure points for all stakeholders confronting unexpected serious safety incidents, there is a collaborative effort to encourage and implement a global Independent Investigation process and mechanism.

Mary F Tobin, PhD
Alliance for Clinical Research Excellence and Safety



Conceptual thinker and developer. Entrepreneurial mindset and organization builder. Identify core issues and design solutions. Multi-discipline researcher and integrator. No-nonsense advisor. Mediator and Writer.

As Chief Strategy Officer and Special Advisor to the President/CEO at the Alliance for Clinical Research Excellence and Safety (ACRES), assist this global non-profit organization to build a sustainable, interconnected and interoperable global system for clinical research, one built by clinical research stakeholders worldwide, to enhance safety, data quality and integrity to improve the health and lives of everyone. As Managing Director of IMPACT LLC, bring professional services to Life Sciences industry clients and U.S. HHS Operating Divisions, including FDA and NIH.

Missed Opportunities and Proposed Solutions
The efforts to include patients in clinical research is a laudable goal, one which would positively impact drug safety and patient satisfaction. Achieving it requires a more comprehensive understanding of the patient environment than frequently occurs.

Veronika Valdova

Veracuity LLC & Arete-Zoe, LLC

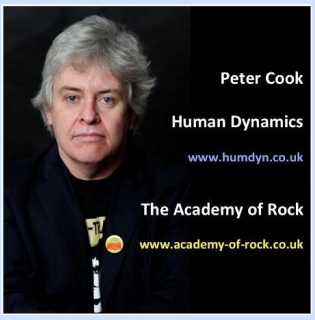
Veronika Valdova, a veterinarian by education, is the co-founder of Veracuity, LLC and managing partner at Arete-Zoe, LLC. She spent most of her career in various roles in drug safety and clinical research. Her experience includes all aspects of pharmacovigilance operations from case processing to compiling safety reports and analyses and reviewing and evaluating scientific literature. Her current endeavors include the preparation of reports required for re-certification of medical devices for the EU market. She authored numerous professional courses and training programs. She is passionate about the operational costs of drug safety surveillance and the quality of intelligence drug safety monitoring activities can provide.

Avoidable Patient Harm and Resulting Liability

Quantifying the cost of patient harm remains a challenge. Reduced visibility of Adverse Drug Events makes it difficult for physicians to adjust their prescribing practices, which extends occurrence of preventable error related injuries, with associated liability risk.

Peter Cook

Human Dynamics, The Academy of Rock



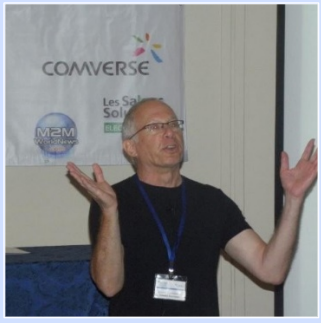
Peter Cook leads Human Dynamics, offering Business and Organisation Development. He also delivers keynotes around the world that blend business intelligence with parallel lessons from music via The Academy of Rock. Author of and contributor to eleven books on business leadership. His three passions are science, business and music, having led innovation teams for 18 years to develop life-saving drugs including the first treatments for HIV / AIDS, Herpes and the development of Human Insulin. 18 years in academia and 18 + years running his businesses. All his life since the age of four playing music.

Innovation: Sex, Pharmaceuticals and Rock and Roll

I'm offering an innovation masterclass with some parallel insights from the field of music. At the same time I'll relate these to the pharma industry based on my experience of scale up of products from Human Insulin to the first treatments for Herpes and HIV/AIDS. The session will be both informative and enjoyable.

Danny Lieberman

Flaskdata.io



I am a solid-state physicist by training, serious amateur musician and entrepreneur heavily involved in medical device security and use of AI for assuring patient compliance to clinical protocols in clinical trials. I'm proud to be working with some very smart people, all smarter than me. Contact me at any time on LI if you have ideas for new ventures or partnerships.

Fast data and compliance automation for clinical trials

I am founder and CEO of flaskdata.io – fast signal acquisition and automated detection and response for clinical trials.

Steven Beales
SVP, Scientific & Regulatory, WCG Clinical

An expert in field of safety reporting technology, Mr. Beales has over 20 years experience in the pharmaceutical industry. In 2009, Roche asked him to build the largest SafetyPortal in the world, which has distributed over 100m safety notifications in over 100 countries according to local regulatory intelligence in each country. Subsequently, Mr. Beales extended this work to Janssen and to Covance and is now focused on democratizing this technology for emerging biopharma. Mr. Beales is co-chair of the Safety Reporting Harmonization Working Group. Prior to joining WCG, Mr. Beales led the implementation of the CTMS systems for Johns Hopkins University, and Washington University at St. Louis, and the Interactive Autism Network.

Global Safety Reporting according to Local Laws
How sponsors are moving towards harmonized business models that distribute the right safety information to right person at right time anywhere in world using local laws and latest technologies.

Stephen Mott
Keep Me Informed

Stephen's background is in the life science industry and medical information. A graduate in Human Biology and Anatomy, Stephen was responsible for developing the electronic Medicines Compendium for the Association of the British Pharmaceutical Industry, and for producing medicines information content for NHS Choices website. Steve founded Keep Me Informed Ltd which keeps patients up to date about the conditions and medicines they are interested in. Steve is also a founder of The Pharma Knowledge Group (PKG) in the UK that partners the US company DrugLogic and has developed a powerful probability engine that enables clinicians to identify likely causes of ADRs.

At last, identifying the causes of ADRs at the point of consultation
Decision support system for clinicians to identify adverse drug events and rank causal relationship probability and identify alternate drug or therapeutic class choices. The aim is to reduce the burden of ADRs on health systems.

Robert Durham
Market Staging Inc., Agenus, Inc.

Turbocharge Your Pharmacovigilance Data Collection & Analysis with Accreditation & HIE

What is a Medication Error?

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use. The Joint Commission of the The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) requires tracking of medication management measures as well as patient-safety measures for medication incidents as part of acute care facility accreditation processes. We have worked with over 250 acute care facilities in the US for 20 years providing accreditation tracking software used to comply with The Joint Commission Standards. A subset of this experience has focused on support for medication errors tracking. The collection of accreditation specific errors, defined as a pharmacovigilance cohort, combined with Health Information exchange (HIE) interoperability provides a path for both managing costs and laying a foundation for the future of pharmacovigilance reform.

Jane Ginn
Cyber Threat Intelligence Network (CTIN)

Ms. Ginn has over 30 years of international business experience in engineering consulting, information technology, and cyber security threat intelligence. She serves as Secretary of the OASIS Cyber Threat Intelligence – Technical Committee (CTI TC) on STIX/TAXII standards development. She is also an adviser to the European Network Information & Security Agency (ENISA) Threat Landscape Stakeholders' Group. She also serves on the Board of Directors of the Cyber Resilience Institute (CRI), the primary sponsor of the Sports-ISAO and on the ENISA group from 2015 through 2018.

Using Cyber Threat Analysis for Pharmacovigilance
Establishing Priority Intelligence Requirements to drive threat hunting activity. We will focus on these three objectives: 1) Intellectual Property theft, 2) Supply-chain weaknesses, 3) Customer database privacy.

Christopher Robinson
Digital Solutions Consultant

Christopher Robinson, PMP, ITIL, is an IT Transformation Project Manager for enterprise software solutions and global workflow optimization and process automation, in the HealthCare and Financial sectors. He works as a Healthcare website administrator And a Cybersecurity researcher.

Personal Health Information (PHI) Policy Across Global Teams
Establishing PHI workflow policies across workforces and systems, and implementing governance across teams

Sreeram Penna
Founder and Chief Medical Officer at Veracuity LLC

Dr. Sreeram Penna has more than 15 years of experience as a clinician and researcher. He worked in orthopedic surgery and his research interests include big data, machine learning and artificial intelligence concepts in health care. He has experience in generating real-world evidence using social media data to be used in health care research. He would like to bring this experience in pharmacovigilance.

The Role of Social Media in Pharmacovigilance
Social media contain wealth of information about individuals including their wealth. Social media mining for pharmacovigilance is an emerging concept with potential to generate vast amount of data.

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