Virtual Workshop II

Innovative Approaches to Drug Safety

You are cordially invited to join our workshop to participate in insightful conversation on the future of our industry

JANUARY 29TH, 2021
7 AM EST & 1 PM EST

Introduction and closing remarks:
Jonathan M. Fishbein, MD
Founder and President at Veracuity, LLC

Session 1:
Carla Perdun Barrett, PharmD
Senior Director, Patient Safety & Risk Management at PRA Health Sciences

Session 2:
Isabelle Laugel
CEO & Principal Consultant at Life Sciences Expertise

Session 3:
Michael Marschler
Compliance and EU Lead at Veracuity, LLC

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SESSION 1

Implementation of Post-marketing Risk Management Commitment

Numerous approaches exist to manage patient risk, including additional risk minimization measures such as communication and educational materials. Multiple techniques exist to implement additional risk minimization measures. These methods may vary in countries and regions with different healthcare systems and diverse approaches to the practice of medicine, pharmacy, and patient care which pose unique challenges and opportunities. Effective strategies to implement and monitor the global implementation of additional risk minimization measures to minimize risks to patients will be described. Best practices will provide practical advice to navigate these unique opportunities.

Carla Perdun Barrett, PharmD
Senior Director, Patient Safety & Risk Management at PRA Health Sciences

Carla Barrett is a pharmacovigilance risk management expert with 20 years of pharmaceutical industry experience, including 15 years dedicated to pharmacovigilance risk management. She is the former Head of the Risk Management Center of Excellence at Pfizer and the former Head of Global Risk Management at Allergan where she provided strategic input to over 100 global risk management strategies including Risk Evaluation and Mitigation Strategies (REMS), European Union Risk Management Plans (EU-RMPs), and local RMPs for products in development, as well as marketed products. Carla's other pharmaceutical industry experience includes Senior Director & Head, Safety Sciences Research at Pfizer and Senior Director of Risk Management at Wyeth Pharmaceuticals. Carla also has extensive expertise in Medical Information and Medical Communications working in Global Medical Affairs at Wyeth, as an independent consultant working with clients in the academic, healthcare, and pharmaceutical industries, and in traditional hospital pharmacy practice and drug information.

SESSION 2

The future of pharmacovigilance with the use of artificial intelligence sounds good

On one hand, pharmacovigilance has to deal with an ever-increasing volume of data to process and on the other hand, artificial intelligence (AI) is emerging as the way to manage the gigantic amounts of data generated by our digital world. It is therefore natural that the pharma industry is increasingly looking toward AI to manage these imperatives. The pharmaceutical industry cannot go on facing this challenge just by increasing the human resources dedicated to process data. This presentation highlights the opportunities AI offers to pharmacovigilance, in the short, medium and long term. It goes all the way from a specific example to the exposure of the difficulties to be overcome in order to reach the required level of quality and comply with the regulations. Discover the potential of AI in PV, while being aware of the challenges involved in shipping it into production.

Isabelle Laugel
CEO & Principal Consultant at Life Sciences Expertise

Isabelle Laugel is a mathematician and software developer, specialized in security of computer systems and optimization, she is working in the pharmaceutical industry since over 20 years providing training, validation, consulting and support services for life sciences software and business processes to pharmaceutical companies, medical devices companies and CROs of any size worldwide. She founded Life Sciences Expertise in 2011 in order to share her experience in clinical data management and drug safety, in both human health and animal health. Life Sciences Expertise is continuously growing, proposing new services and products, related to the processing and evaluation of data.

SESSION 3

The use of Pharmacogenomic Methodologies in the Pharmacovigilance Evaluation of Medicinal Products

The presentation provides considerations on the influence of pharmacogenomics on Pharmacovigilance activities including but not limited to Risk Management Planning and Benefit Evaluation. This includes information on how to evaluate Pharmacovigilance related issues for medicinal products with pharmacogenomic associations and how to translate the results of these evaluations to appropriate treatment recommendations. Due to gene-environmental interactions there exists large variability in responses to drug therapy, some of which are inherited or non-inherited characteristics of the genome. Such genomic variations have the potential to lead to subsets of patients with a different benefit/risk profile. It would therefore be important to consider genomic variations and explore the methods for collecting genomic data. In the pre-marketing stage, a medicinal product is exposed to a relatively small number of subjects due to the confines of the clinical trial. As such, rare and/or serious adverse drug reactions (ADRs) may only be identified later in the drug development process. Considerations should be made to identify sub-populations who may have increased or decreased sensitivity to medicinal products as a result of genomic factors. Doing so has the potential to greatly reduce the risk of side effects and significantly increase the therapeutic benefit to the subjects. During the process, and preparation, of risk management plans (RMP) it is essential to consider the potential risk of genomic variations and identify risk minimizations measures.

Michael Marschler
Compliance and EU Lead at Veracuity, LLC

Michael Marschler is a pharmacovigilance expert by training. He worked in various roles in the Pharmaceutical and CRO industries, providing leadership to his direct reports and to project teams. His experience includes all aspects of pharmacovigilance from case processing and aggregate safety reporting to risk management and signal management, as well as process development to ensure regulatory compliance. During the last years he focuses on pharmacogenomics and how to integrate PGx within pharmacovigilance. He served as EU QPPV and most recently as Sr. Director Pharmacovigilance and Global Head of Patient Safety Operations at PRA Health Sciences. Michael Marschler is a member of the Steering Committee and Scientific Advisory Board of The Santorini Conferences and member of the Board of Editors of two scientific publications.

Veracuity Team

Jonathan M. Fishbein, MD
Founder and President at Veracuity, LLC

Dr. Sreeram Penna, MBBS
Founder and Chief Medical Officer

Veronika Valdova, DVM
Founder and Chief Scientific Officer

Veracuity was conceived out of a recognition that the practice of pharmacovigilance is performed suboptimally. That is because it relies entirely on a voluntary reporting system – one in which consumers and healthcare professionals must devote considerable energy if they were so inclined to notify somebody about a side effect they attribute to a bio-pharmaceutical product. Adverse event reporting is infrequent and cumbersome because stakeholders are only vaguely aware of their responsibility and the current system is neither easy nor fast to use. Nor does it provide reporters with any immediate helpful feedback. With only a very small percentage of adverse drug events ever reaching the attention of manufacturers or regulators, it is easy to conclude that the medical community and the public may be wholly unaware of tremendous risks and liabilities that may be attributed to drug products.

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