## INNOVATIVE IDEA GENERATING CENTRE

# PHARMACOVIGILANCE AND RISK MANAGEMENT VIRTUAL CONFERENCE 2025

25 JUNE 2025 | VIRTUAL CONGRESS (BST)

## KEY TOPICS ON THIS YEAR'S AGENDA INCLUDE:

- EMERGING TECHNOLOGIES IN PHARMACOVIGILANCE – EXPLORING AI, BIG DATA ANALYTICS, AND REAL-WORLD DATA TO ENHANCE DRUG SAFETY MONITORING.
- TACKLING UNDERREPORTING AND ENHANCING COLLABORATION – STRATEGIES TO IMPROVE ADVERSE EVENT REPORTING THROUGH DATA SHARING AND CROSS-SECTOR PARTNERSHIPS.
- BIG DATA AND RISK MANAGEMENT IN DRUG SAFETY – LEVERAGING MACHINE LEARNING AND DATA-DRIVEN APPROACHES FOR IMPROVED PHARMACOVIGILANCE.
- PERSONALIZED MEDICINE AND PHARMACOVIGILANCE – ADDRESSING CHALLENGES IN MONITORING ADVERSE EVENTS IN PRECISION THERAPEUTICS.
- AI AND MACHINE LEARNING IN DRUG SAFETY SURVEILLANCE – EXAMINING HOW AI IMPROVES REAL-TIME MONITORING AND PREDICTIVE ANALYTICS FOR RISK ASSESSMENT.
- POST-MARKET DRUG SAFETY MONITORING – THE ROLE OF CONTINUOUS SURVEILLANCE AND REAL-WORLD EVIDENCE IN ENSURING LONG-TERM PATIENT SAFETY.
- PATIENT-CENTERED
   PHARMACOVIGILANCE INTEGRATING
   PATIENT-REPORTED OUTCOMES WITH
   TRADITIONAL MONITORING SYSTEMS FOR
   BETTER SAFETY INSIGHTS.
- RARE ADVERSE DRUG REACTIONS: DETECTION AND MANAGEMENT – ENHANCING PHARMACOVIGILANCE STRATEGIES FOR IDENTIFYING AND PREVENTING RARE SAFETY RISKS.
- THE FUTURE OF PHARMACOVIGILANCE: MOVING TOWARDS PROACTIVE SAFETY SYSTEMS – HOW PREDICTIVE ANALYTICS AND GLOBAL COLLABORATION ARE SHAPING NEXT-GENERATION DRUG SAFETY.

#### **SPEAKERS:**

- Lizanne Pistorius Head of Patient Safety & Pharmacovigilance **Boehringer Ingelheim**
- Gurpreet Singh Vice President, Managing Director Integrated Safety IQVIA
- Valentina Mancini Senior Director, Pharmacovigilance & QPPV Shionogi Europe
- Sanket Mahajan Safety Scientist, Pharmacovigilance Shionogi Europe
- Michael Von Forstner Head of Global Safety Science Sobi
- David Gillen Chief Medical Officer Norgine
- Giovanni Furlan Senior pharmacovigilance professional
- Geeta N. Shanbhag Vice President Pharmacovigilance & Medico-regulatory affairs Ipca Laboratories Ltd.
- Dimitris Zampatis Director Product Patient Safety-TA Oncology and Immunology Sandoz
- Erika Barbarosie Associate Director Compliance R&D Quality
- Galyna Cordero Head Of {Pharmacovigilance Department, Qppv Jsc
   Farmak
- Akhilesh Chamediya Global Medical Director Patient Safety Alexion Pharmaceuticals, Inc.



Exploring innovative pharmacovigilance approaches to enhance patient safety, optimize risk management, and ensure regulatory compliance worldwide.

25 June 2025

Pharmacovigilance (PV) and risk management are integral components of drug safety and regulatory compliance. The ever-evolving landscape of pharmaceuticals, biologics, and medical devices demands continuous adaptation to emerging safety concerns, regulatory updates, and technological advancements. The "Revolutionizing Pharmacovigilance and Risk Management" Conference 2025 aims to bring together key stakeholders, industry leaders, regulatory authorities, healthcare professionals, and technology innovators to discuss and shape the future of pharmacovigilance. This document outlines the key reasons for hosting this conference and its anticipated impact on the industry.

#### Addressing Global Pharmacovigilance Challenges

In recent years, the pharmaceutical industry has faced numerous challenges, including increased regulatory scrutiny, growing patient awareness, and the need for real-world evidence (RWE) to support drug safety decisions. The conference will provide a platform to discuss critical challenges such as:

 Regulatory Complexity: Understanding and complying with diverse global pharmacovigilance regulations.

 Technological Advancements: The integration of artificial intelligence (AI), machine learning (ML), and automation in PV processes.

 Data Management & Real-World Evidence: Leveraging big data and real-world evidence for better decision-making.

Patient-Centric Pharmacovigilance: Engaging patients in adverse event reporting and monitoring.

• Global Safety Concerns: Addressing emerging safety signals and rapid responses to adverse drug reactions (ADRs).



Facilitating Knowledge Exchange and Best Practices

The conference aims to facilitate knowledge sharing among experts and industry professionals by featuring:

Keynote addresses from global leaders in pharmacovigilance.

- Panel discussions on regulatory updates from agencies like the FDA, EMA, MHRA, and WHO.
- Case studies on successful risk management strategies.
- Workshops on implementing AI and automation in PV operations.

**Embracing Technological Innovation** 

The rise of digital health, Al-driven safety monitoring, and blockchain for data security presents opportunities to enhance pharmacovigilance efficiency. This conference will highlight:

- The role of AI and predictive analytics in adverse event detection.
- Automation in case processing and signal detection.
- Blockchain technology for secure and transparent data sharing.
- The potential of mobile health (mHealth) applications in pharmacovigilance.

Strengthening Regulatory Compliance

Pharmacovigilance regulations continue to evolve, requiring companies to stay updated to ensure compliance. The conference will help stakeholders understand:

- Recent changes in international PV regulations.
- Best practices for complying with Good Pharmacovigilance Practices (GVP).
- The impact of regulatory changes on pharmaceutical business strategies.

**Enhancing Patient Safety and Public Health** 

At its core, pharmacovigilance is about ensuring patient safety and improving public health outcomes. Through expert discussions and collaborative sessions, the conference will:

- Promote proactive risk management strategies.
- Encourage transparent and effective communication with healthcare providers and patients.
- Foster partnerships to enhance global drug safety monitoring.

Innovative Strategies in Pharmacovigilance: Safeguarding Patients and Streamlining Compliance 25 June 2025

#### Strengthening Industry Collaborations and Networking

The conference will serve as a hub for collaboration, bringing together key players in the pharmacovigilance ecosystem, including:

- Pharmaceutical companies and biotechnology
- Regulatory agencies and policymakers.
- Healthcare providers and patient advocacy groups.
- Technology providers offering innovative PV solutions.

The Revolutionizing Pharmacovigilance and Risk Management Conference 2025 is essential in fostering innovation, ensuring compliance, and improving patient safety. By providing a platform for industry experts, regulators, and technology innovators to exchange ideas, discuss challenges, and collaborate on solutions, this conference will drive the future of pharmacovigilance forward. Through knowledge sharing, regulatory discussions, and the integration of cutting-edge technologies, this event will play a pivotal role in shaping the next era of drug safety and risk management.



#### Who should attend:

#### Pharmacovigilance & Drug Safety

Head/Director/VP of Pharmacovigilance

- Drug Safety Officer/Specialist Pharmacovigilance Scientist

- Risk Management Specialist Signal Detection & Management Lead
- Safety Surveillance Manager

# Regulatory Affairs & Compliance Regulatory Affairs Manager/Director • Compliance Officer/Manager

- Regulatory Intelligence Specialist
- Quality Assurance Manager
- Clinical Safety & Compliance Director
   Clinical Research & Development
   Clinical Research Associate (CRA)

- Clinical Trial Safety Specialist
- **Medical Monitor**

## Clinical Data Manager Medical Affairs & Risk Management

- Chief Medical Officer (CMO)
- **Medical Director**
- Risk Evaluation & Mitigation Strategies Lead
- **Epidemiologist**
- Technology & Data Science in PV Drug Safety Data Analyst
- AI & Automation Specialist in PV
- Signal Detection & Data Science Lead



Discover how emerging technologies, data-driven strategies, and regulatory advancements are reshaping adverse event detection and patient safety worldwide.

25th June 2025

#### 09:00 Pharmacovigilance: Current Trends, Emerging Challenges, and Opportunities for Advancing Drug Safety and Regulatory Practices.

This presentation explores the latest trends in pharmacovigilance, including advancements in artificial intelligence, real-world evidence, and global harmonization of safety regulations. Key challenges such as data management complexities, adverse event reporting limitations, and evolving regulatory landscapes will be discussed. Additionally, the session will highlight emerging opportunities to enhance drug safety through proactive risk management strategies, improved stakeholder collaboration, and innovative technological solutions.

Gurpreet Singh Vice President, Managing Director Integrated Safety **IQVIA** 

09:25 Questions & Discussion

09:30 Leveraging Quality Management Systems to Improve Pharmacovigilance Processes: A Comprehensive Approach to Ensuring Drug Safety and Compliance

Lizanne Pistorius Head of Patient Safety & Pharmacovigilance Boehringer Ingelheim

09:55 Questions & Discussion

A New Era of Drug Safety Panel Discussion: 10:00 Strengthening Pharmacovigilance for Effective Drug Safety Monitoring: Tackling Underreporting and Promoting Collaborative Solutions.

Best Practices in Global Drug Safety –
 Showcasing innovative strategies to enhance risk management and patient-centric pharmacovigilance approaches.

Galyna Cordero Head Of Pharmacovigilance Department, Qppv Jsc **Farmak** 

- Real-World Data Utilization Examining the impact of real-world evidence and patientgenerated data in detecting adverse drug reactions.
- Regulatory Advancements Understanding the evolving regulatory landscape and its role in enhancing pharmacovigilance practices.

Collaborative Networks & Data Sharing –
 Highlighting the importance of cross-sector
 partnerships in strengthening global drug safety.

Valentina Mancini Senior Director, Pharmacovigilance & QPPV **Shionogi Europe** 

- Real-Time Monitoring for Rapid Response –
   Exploring technologies that enable proactive risk management and real-time adverse event tracking.
- AI-Driven Signal Detection Discussing how artificial intelligence improves the speed and accuracy of adverse event detection.

Dimitris Zampatis Director Product Patient Safety-TA Oncology and Immunology **Sandoz** 

11:00 Interactive Discussion

11:30 Refreshment Break

## 12:00 Use of AI in Automation of Signal Detection tool

- Introduction and description of a new probabilistic method for causality assessment
- Automation of the tool by means of Large Language Models and predefined datasheets
- Comparing the outcomes of automated (Aldriven) vs manual (human) assessment
- Exploring future use of the tool for conducting an automated semi-quantitative signals detection

Sanket Mahajan Safety Scientist, Pharmacovigilance **Shionogi Europe** 

12:25 Questions & Discussion

## 12:30 The Future of Pharmacovigilance: From Reactive to Proactive Safety Systems

This discussion provides insights into the evolution of pharmacovigilance from traditional reactive approaches to advanced proactive safety systems. It will highlight the role of emerging technologies, real-world data, and predictive analytics in identifying and mitigating drug safety risks before they escalate. Attendees will gain insights into how regulatory frameworks, artificial intelligence, and global collaboration are shaping the next generation of patient safety monitoring.

Geeta N. Shanbhag Vice President Pharmacovigilance & Medico-regulatory affairs **Ipca Laboratories Ltd.** 

12:55 Questions & Discussion

Discover how emerging technologies, data-driven strategies, and regulatory advancements are reshaping adverse event detection and patient safety worldwide.

25th June 2025

13:00 LUNCH BREAK

Panel Discussion on Risk Management Plans 14:00 Strengthening Safety Measures from Drug Development to Regulatory Approval for Optimal Patient Protection

 Global Pharmacovigilance Regulations -Ensuring Compliance and Safety through International Standards and Requirements.

Erika Barbarosie Associate Director Compliance **R&D Quality** 

- Ensuring Regulatory Success Optimizing Pharmacovigilance Approaches to Meet Market Authorization Standards and Ensure Comprehensive Drug Safety.
- Collaboration and Reporting Uncovering Effective Stakeholder Communication Strategies for Ensuring Transparency and Promoting Drug Safety Initiatives.
- Advanced Detection of Adverse Drug Reactions (ADRs) - Examining Cutting-Edge Strategies for Detecting and Mitigating Adverse David Gillen Chief Medical Officer Norgine Drug Reactions.
- Effective Risk Mitigation in Clinical Trials -Delving into Strategies for Proactively Addressing Drug-Related Safety Chállenges.
- Protecting Patient Safety Analyzing Strategies for Monitoring and Ensuring Safety from Early Trials to Approval.

Akhilesh Chamediya Global Medical Director Patient Safety Alexion Pharmaceuticals, Inc.

15:00 Interactive Discussion

15:30 Refreshment Break

## 16:00 Enhancing Drug Safety through Patient Simplicity: Communication Approaches for Informed Benefit-Risk Decision

This session will explore the critical role of clear and effective communication in empowering patients to make informed decisions about their treatment options. By simplifying complex medical information, healthcare professionals can improve patient understanding of drug safety, benefit-risk profiles, and potential adverse effects. The talk will focus on stratogics for presenting information in focus on strategies for presenting information in an accessible, patient-friendly format, using visuals, plain language, and tailored messaging.

We will discuss how these approaches can enhance patient engagement, promote shared decisionmaking, and ultimately improve patient outcomes. Attendees will learn best practices for communicating the benefit-risk balance of medications, ensuring patients are well-informed and able to actively participate in their healthcare decisions.

Michael Von Forstner Head of Global Safety Science Sobi - Swedish Orphan Biovitrum AB (publ)

### 16:30 Patient-Centered Pharmacovigilance: Bridging the Gap Between Reporting and Real-World Evidence

This talk explores the evolving role of patients in pharmacovigilance, emphasizing the importance of real-world data in enhancing drug safety. By integrating patient-reported outcomes with traditional reporting systems, we can bridge the gap between adverse event reporting and actionable real-world evidence. The session will highlight innovative strategies, emerging technologies, and collaborative approaches to make pharmacovigilance more pätient-centered and impactful.

16:55 Questions & Discussion

#### 17:00 AI Will Revolutionize PV As We Know It Today But Does Anyone Know How To Validate It?

- Regulatory requirements for using AI in pharmacóvigilance
- Principles of how large language models work
- Planning, executing and documenting Al validation

Giovanni Furlan Senior pharmacovigilance professional

17:25 Questions & Discussion

17:30 End of conference

## Pharmacovigilance and Risk Management Virtual Conference 2025 25 June 2025 | VIRTUAL CONGRESS(BST)

### **Registration Form**

Delegate Registration Standard Prices: £650

#### How to register for the conference:

registration@innovative-idea-generating-centre.com

Address: 321-323 High Road, Romford, RM6 6AX, Essex,

**United Kingdom** 

Telephone: +44 20 3239 7600

Name:		Phone Number:	
Job Title:		Mobile Number:	
Company Name:		Email Address:	
Company Address (1)		Signature:	
Company Address (2)			
City			
Postcode:			
Country			

#### **General information**

How to Join the virtual conference:

One week before the conference, you will receive a virtual link and password to access the online platform.

Payment: Your invoice must be paid within 7 days of the issue date. If you are unable to attend the conference, you may appoint a substitute. A recording will also be available for 30 days after the event.

How we will contact you: IIGC preferred method of communication is by email and phone. Please ensure that you complete the registration form in full so that we can contact you.