

REVOLUTIONIZING PHARMACOVIGILANCE AND

RISK MANAGEMENT CONFERENCE

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.

Early Confirmed Speakers:

- Lizanne Pistorius Head of Patient Safety & Pharmacovigilance Boehringer Ingelheim
- Gurpreet Singh Vice President, Managing Director Integrated Safety IQVIA
- Sanket Mahajan Safety Scientist, Pharmacovigilance Shionogi Europe
- Michael Von Forstner Head of Global Safety Science Sobi
- David Gillen Chief Medical Officer Norgine
- Giovanni Furlan Worldwide Safety Site Lead Pfizer
- Geeta N. Shanbhag Vice President Pharmacovigilance & Medico-regulatory affairs Ipca Laboratories Ltd.

Super Early Bird Registration Price: £250 (Super Early Bird pricing ends 10 April 2025)

09:00am (BST) 25 JUNE 2025





REVOLUTIONIZING PHARMACOVIGILANCE AND RISK MANAGEMENT

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.

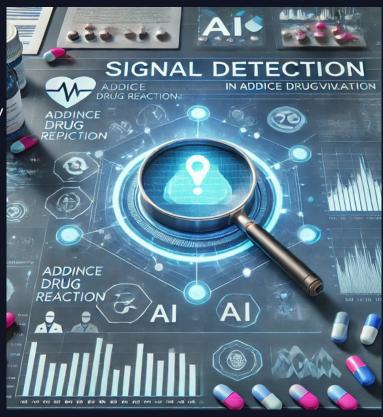
REVOLUTIONIZING PHARMACOVIGILANCE AND RISK MANAGEMENT Innovative Strategies in Pharmacovigilance: Safeguarding Patients and Streamlining Compliance 25 June 2025

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 firms.
- 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

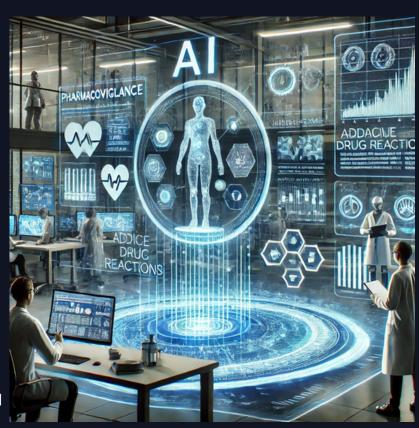
- Regulatory Intelligence Specialist
- Quality Assurance Manager
- Clinical Safety & Compliance Director
 Clinical Research & Development

- 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 Al & Automation Specialist in PV
- Signal Detection & Data Science Lead



REVOLUTIONIZING PHARMACOVIGILANCE AND RISK MANAGEMENT CONFERENCE

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.

- Emerging Technologies in Pharmacovigilance Exploring how AI, big data analytics, and automation are revolutionizing drug safety monitoring.
- 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.

- Al-Driven Signal Detection Discussing how artificial intelligence improves the speed and accuracy of adverse event detection.
- Collaborative Networks & Data Sharing Highlighting the importance of cross-sector partnerships in strengthening global drug safety.
- Real-Time Monitoring for Rapid Response Exploring technologies that enable proactive risk management and real-time adverse event tracking.
- Best Practices in Global Drug Safety Showcasing innovative strategies to enhance risk management and patient-centric pharmacovigilance approaches.

11:00 Refreshment Break

11:30 Exploring the Role of AI and Machine Learning in Drug Safety Surveillance

This session delves into how artificial intelligence and machine learning are transforming drug safety surveillance. From detecting adverse drug reactions to predicting potential risks, AI-driven approaches are enhancing pharmacovigilance by improving data analysis, real-time monitoring, and regulatory decision-making. Join us to explore cutting-edge advancements, challenges, and future directions in leveraging AI for safer medicines and better patient outcomes.

11:55 Questions & Discussion

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

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12:30 The Future of Pharmacovigilance: From 15:00 Enhancing Drug Safety through Patient Reactive to Proactive Safety Systems

This discussion provides insights into the evolution of pharmacoviģilance from traditional reactive approaches to advanced proactive safety systems. It will highlight the role of emerging

Pharmacovigilance & Medico-regulatory affairs Ipca Laboratories Ltd.

12:55 Questions & Discussion

13:00 Break

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

- 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 Drug Reactions.
- Global Pharmacovigilance Regulations -Ensuring Compliance and Safety through International Standards and Requirements.
- Effective Risk Mitigation in Clinical Trials -Delving into Strategies for Proactively Addressing Drug-Related Safety Challenges.
- Protecting Patient Safety Analyzing Strategies for Monitoring and Ensuring Safety from Early Trials to Approval.

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 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

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 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 decision-making and ultimately promote shared decision-making, 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)

15:25 Questions & Discussion

15:30 Refreshment Break

16:00 Harnessing Big Data for Effective Pharmacovigilance and Risk Management.

This talk explores how big data analytics is transforming pharmacovigilance and risk management in the pharmaceutical industry. It will cover innovative data-driven approaches to detecting adverse drug reactions, improving patient safety, and ensuring regulatory compliance. Attendees will gain insights into leveraging real-world data, artificial Reactions (ADRs) – Examining Cutting-Edge insights into leveraging real-world data, artificial Strategies for Detecting and Mitigating Adverse intelligence, and machine learning to enhance drug safety monitoring and decision-making.

16:25 Questions & Discussion

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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 patient-centered and impactful.

David Gillen Chief Medical Officer Norgine

16:55 Questions & Discussion

17:00 Pharmacovigilance in the Era of Personalized Medicine: Challenges and Opportunities

This session investigates how tailored treatments impact drug safety monitoring, the role of realworld data and AI in adverse event detection, and strategies to enhance regulatory frameworks. Attendees will gain insights into adapting pharmacovigilance practices to ensure patient safety in an era of precision therapeutics.

17:25 Questions & Discussion

17:30 Pharmacovigilance in the Post-Market Phase: Monitoring Long-Term Drug Safety

This session explores the critical role of pharmacovigilance in the post-market phase, focusing on the continuous monitoring of drug safety beyond clinical trials. Attendees will gain insights into adverse event reporting, real-world data analysis, and regulatory requirements to ensure long-term patient safety and effective risk management.

17:55 Questions & Discussion

18:00 End of conference

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Registration Form

Super Early Bird Registration Price: £250 (Super Early Bird pricing ends 10 April 2025)

Early Bird Registration Price: £450 (Early Bird pricing ends 10 May 2025)

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: <u>+44 20 3239 7600</u>

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.