



23 - 24 September

2025

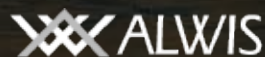
Mumbai  
India

Updated: 17 September, 2025

for the latest programme update, please  
download agenda on conference website

# 2<sup>nd</sup> Global Drug Safety & PV Outsourcing Summit 2025

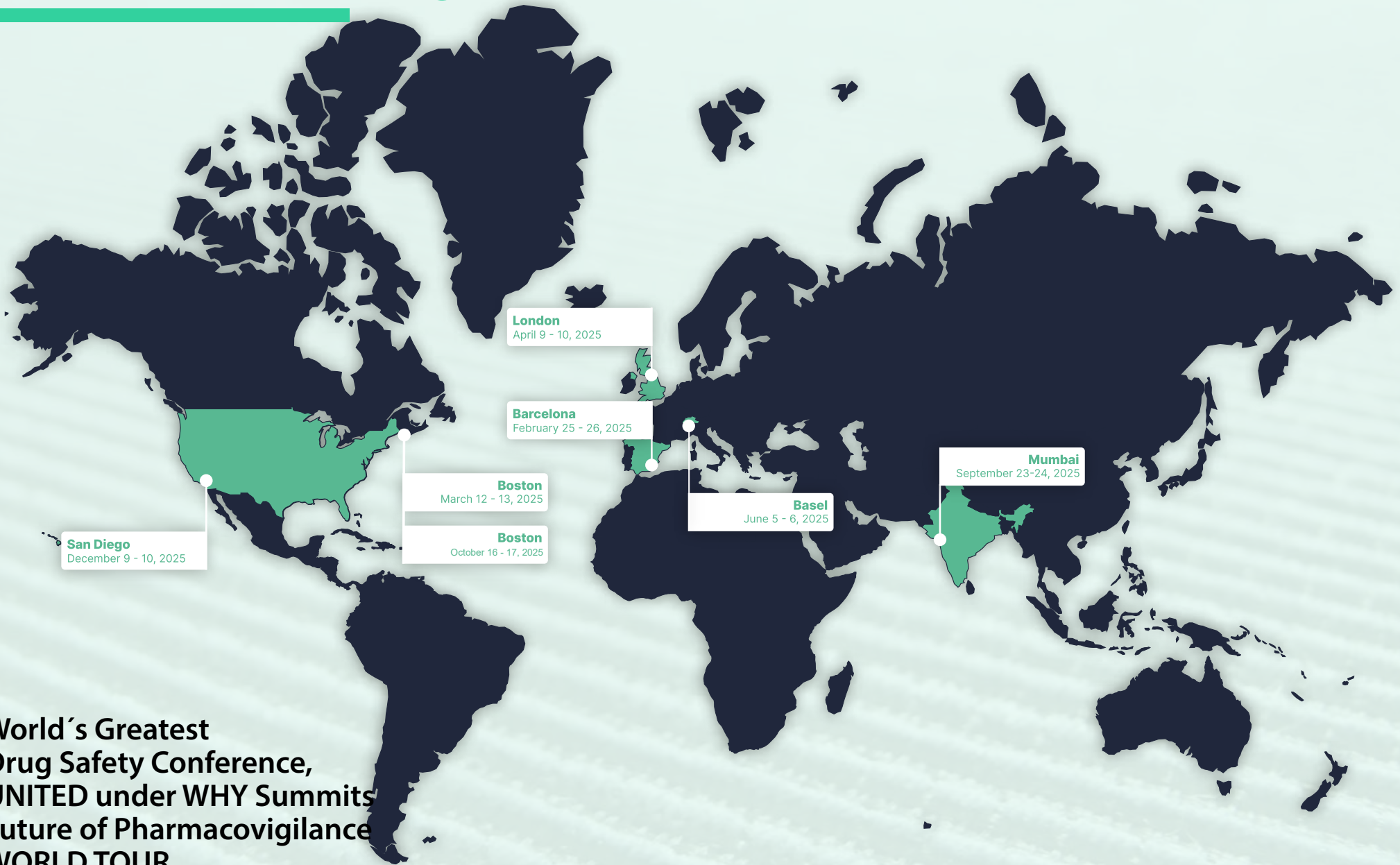
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# 2025 Pharmacovigilance Summits Worldwide



World's Greatest  
Drug Safety Conference,  
UNITED under WHY Summits  
Future of Pharmacovigilance  
WORLD TOUR

Our prestigious Drug Safety Summit, a cornerstone of our Pharmacovigilance World Tour.

- 📌 **Meet** top Drug Safety professionals from our 2025 World Tour
- 📌 **Learn** about the most important issues that need to be addressed
- 📌 **Discuss** the vision for 2025 and lessons of 2024
- 📌 **Listen** to the most crucial current topics selected & presented by industry leaders
- 📌 **Enjoy** education & networking focused event in a non-vendor-driven environment
- 📌 **Create** lasting work groups and friendships with the possibility of meeting regularly on the next stops of our world tour

## You will spend your time with

- 📌 **Drug safety & Pharmacovigilance executives**
- 📌 **Heads of global safety programs**
- 📌 **Benefit-Risk assessment management**
- 📌 **Medical affairs management**
- 📌 **Patient safety management**
- 📌 **Compliance specialists**
- 📌 **Post-market researchers**
- 📌 **PV auditors**
- 📌 **Regulatory affairs directors**
- 📌 **Compliance specialists**
- 📌 **Pharma IT management**
- 📌 **Safety consultants**

## Always ask WHY?

Creating contrast to loud, expo-style meetings with limited focus and personal touch, WHY SUMMITS World tour of Pharmacovigilance conferences brings another kind of experience. Our Mumbai concentrated knowledge-focused meeting, is assembled in 8 blocks focusing on:

- 📌 **Strategic Overview: 2025 Outlook, Trends And Upcoming Challenges**
- 📌 **Expanding Pipeline & Increased Demand For PV Outsourcing**
- 📌 **Centralized PV Systems To Ensure Inspection-readiness**
- 📌 **Leveraging AI & LLM Technology To Meet Evolving PV Demands**
- 📌 **Aligning Outsourcing Strategy With The Overall Safety Function Strategy**
- 📌 **Advancements In Benefit-risk Assessment And Armms**
- 📌 **Optimizing PV Outsourcing For Post-market Safety Data**
- 📌 **Vendor Selection And Approaches To Effective Management**
- 📌 **Inspection Readiness Through Effective Third Party Management & Oversight**
- 📌 **Patient-centric Approaches In Signal Detection**
- 📌 **Key Considerations For Aligning External PV Services With Internal Workflows**

# Industry Pioneers Attending From



# Testimonials



**Sunil Thakur**

Sr. Manager - Medical Affairs and QPPV  
Exeltis India



"I had the privilege of attending the Global Drug Safety and PV Outsourcing Summit on 22 - 23 October 2024 in Mumbai. It was an incredibly insightful event, packed with valuable discussions and forward-thinking ideas. While many topics were discussed, I found the following particularly important: Cost Center vs. Cost-Effective, Patient-Centric PV, Biosimilars and PV, Leveraging AI and LLM"



**Dr. Santosh Hulawale**

Senior Manager- SERM & PvOI (India)  
Glenmark Pharmaceuticals



"I had the privilege of sharing the stage with industry experts at the recent Global Drug Safety & PV Outsourcing Summit, organized by Why Summits on the topic of 'Challenges in Signal and Risk Management'. The event featured in-depth discussions on a range of topics, including end-to-end pharmacovigilance activities, advances in signal detection, affiliate management, evolving regulations, and more, all offering valuable insights."



**Ismail Ahmed**

Deputy Manager  
Viatris



"Just wrapped up an incredible experience at the Global Drug safety & PV Outsourcing Summit and AI tools (22 to 23 - Oct-2024 in Mumbai). A huge thank you to the organizers #whysummit for their exceptional hospitality and for creating such a welcoming and engaging atmosphere. The insights shared and the connections made were invaluable. From innovative solutions to thought-provoking discussions on the future of outsourcing, this event truly exceeded my expectations."



**Dinesh Wagh**

Manager, Safety Submissions (Clinical Trials)  
Precision For Medicine



"Last week, Attended "Global Drug Safety and PV Outsourcing Summit 2024, Mumbai" as a Speaker and addressed on topic "Advances in Signal Detection & Risk Management". It was a mesmerizing experience ! Thank you Why Summits and Lubos Kusy for inviting !"



**Dr. Shubhadeep D Sinha**

Senior Vice President CD&MA



"Enjoyed it lot. Thanks Why Summits"



**Dr. Deepak S, MD**

Director, Pharmacovigilance- Medical Scientific Unit  
Teva Pharmaceuticals



"I am truly honored to have had the opportunity to moderate such an engaging and thought-provoking panel discussion on "addressing challenges in signal detection and risk management" and "addressing inconsistencies in data reporting and leveraging technology solutions, how technology can help ? at WHY SUMMITS, GLOBAL DRUG SAFETY SUMMIT, MUMBAI."

# Meet the first onboarded speakers to 2025 edition:



**sanofi**

## Dr Vaibhav Salvi

Director and Head –  
Clinical  
Study Unit, India and South  
East Asia R&D – Clinical  
Sciences and Operation

**Sanofi**



**ipca**  
A dose of life

## Geeta N. Shanbhag

Vice President –  
Pharmacovigilance &  
Medico  
-Regulatory Affairs

**Ipca Laboratories Ltd**



**kenvue**

## Dr. Anuja Jawale

Associate Director – Area  
Safety Head - India and  
South Asia Cluster

**Kenvue**



**GSK**

## Kishore Darisi

SERM Associate Scientific  
Director

**GSK**



**zydus**  
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## Dr Devang Patel

Head of Global  
Pharmacovigilance

**Zydus**



**glenmark**

## Rajendra Kumar Kasi

Vice President & Global  
Head – Pharmacovigilance

**Glenmark  
Pharmaceuticals  
Limited**



**SHIONOGI**

## Sanket Mahajan

Safety Scientist,  
Pharmacovigilance

**Shionogi Europe**



**Johnson  
& Johnson**

## Sakshi Shrivastava Desai

Director, LMS regional Lead  
APAC

**Johnson & Johnson**



**WHITE LOTUS**  
INTERNATIONAL  
HOSPITAL & RESEARCH CENTER

## Dr. Rahul S Kamble

Head Quality and Patient  
Safety

**White Lotus  
International Hospital  
and Research Center**



**AMGEN**

## Mukesh Gori

Director Global Patient  
Safety

**Amgen**



**HETERO**

## Dr. Shubhadeep Sinha

Senior Vice-President &  
Medical Director

**Hetero**



**ORGANON**

## Vivek Gupta

Associate Director –  
Strategic Engagements  
& Vendor Management –  
Clinical & Medical Affairs

**Organon**

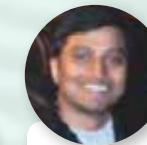


**LUPIN**

## Dr. Priya Prasad

General Manager –  
Pharmacovigilance

**Lupin**



**amneal**

## Dr Sridhar Yeshamaina

Vice President and Global  
Head of Patient Safety and  
Clinical Affairs

**Amneal  
Pharmaceuticals**

# Meet the first onboarded speakers to 2025 edition:



**Rohan Shinde**  
Assistant General  
Manager –  
Pharmacovigilance  
**Jamp Pharmaceuticals**



**Amit Kumar**  
Global Procurement Head,  
Clinical Trials, R&D  
**Novartis**



**Jamal Baig**  
Multi Country Safety Head  
**Sanofi**



**Dr. Girijaa Kadam**  
Director – Global Safety  
Officer  
**Sanofi**



**Joydeep Sengupta**  
GM and Global Head of  
Pharmacovigilance  
**Curateq Biologics**  
(Aurobindo Pharma)

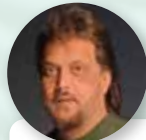


**Chanbasha Shaik**  
Head Global  
Pharmacovigilance

**Chaitanya Kulkarni**  
General Manager –  
Pharmacovigilance  
**Marksans Pharma**



**Shailesh Joshi**  
Senior Director of ICSR  
**Primevigilance**



**Abdul Rahim**  
Founder & Director  
**Alwis Group**



**Ganesh Kumar  
Vemula**  
Vigilance Process Lead  
**Novartis**



**Pooja Payal Singh**  
Director Strategic Accounts  
**Transperfect Life Sciences**



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

In the Chair



**Dr Sridhar Yeshamaina**  
Vice President and Global Head  
of Patient Safety and Clinical  
Affairs  
**Amneal**

## DAY 0 – EVENING BEFORE SUMMIT

### 19:30 MEET & GREET

Informal meeting in the Lobby of the hotel for all attendees coming to the conference the night before. A unique chance to network in tighter, relaxed circles and to register and receive your batch in advance.

### 8:30 Morning Registration and early birds networking coffee

## SUMMIT OPENING: PHARMACOVIGILANCE LANDSCAPE – 2025 TRENDS & CHALLENGES

### 9:00

## OFFICIAL START OF 2<sup>ND</sup> GLOBAL DRUG SAFETY & PV OUTSOURCING SUMMIT WITH OPENING REMARKS OF THE CHAIRPERSON

### 9:10

## OPENING TOWNHALL DISCUSSION: NAVIGATING THE FUTURE OF PHARMACOVIGILANCE:

- Emerging challenges to keep an eye on
- Emerging opportunities & technologies to keep an eye on

### 9:40

## KEYNOTE: KEY TRENDS, INNOVATIONS, AND CHALLENGES AHEAD: WHERE WE ARE AND WHERE DO WE GO FROM HERE?

- Reflections from 2024 to prepare us for 2025
- What's the top-priority for 2025?
- Key focus areas

**Geeta Shanbhag**, Vice President – Pharmacovigilance & Medico-regulatory affairs, Ipca Laboratories Ltd

### 10:10

## RESERVED PRESENTATION FOR ALWIS GROUP

**Abdul Rahim**, Founder & Director, Alwis Group

### 10:40 COFFEE & NETWORKING BREAK

### 11:10

## DRIVING SAFETY THROUGH SYNERGY: A GLOBAL RMP CASE STUDY

- Enhancing communication between PV, clinical, regulatory, and commercial teams
- How cross collaboration can work for effective implementation of risk management
- Transformation and innovation in team dynamics

**Dr. Anuja Jawale**, Associate Director - Area Safety Head - India and South Asia Cluster, Kenvue

### 11:40

## ADDRESSING CHALLENGES IN SIGNAL DETECTION AND RISK MANAGEMENT

- How enabling early detection of potential signals and effective risk management maintains the benefit-risk balance of the product
- Strategies for risk minimisation and communication

**Dr. Girijaa Kadam**, Director - Global Safety Officer, Sanofi

### 12:20

## AUTOMATION OF A PROBABILISTIC SIGNAL DETECTION TOOL WITH THE USE OF AI

- Introduction and description of a new probabilistic method for causality assessment
- Automation of the manual tool by means of Large Language Models (LLM) and predefined datasheets
- Comparing the outcomes of an automated (AI driven) 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

### 13:00 LUNCH BREAK

14:00

## PANEL DISCUSSION: KEY TRENDS, INNOVATIONS, AND CHALLENGES AHEAD IN PV OUTSOURCING

- Structuring scalable governance and oversight frameworks for outsourced PV operations
- Best practices for maintaining inspection readiness and audit trail integrity in hybrid outsourcing models
- Connecting local strategy and global demands in the world of centralized PV processes
- Current challenges in evolving regulatory landscape globally
- Key Drivers for Enabling Centralization - centralization versus outsourcing versus automation

### Panelists:

**Chaitanya Kulkarni**, General Manager – Pharmacovigilance, **Marksans Pharma**

**Mukesh Gori**, Director Global Patient Safety, **Amgen**

**Sakshi Shrivastava Desai**, Director, LMS regional Lead APAC, **Johnson & Johnson**

**Pooja Payal Singh**, Director Strategic Accounts, **Transperfect Life Sciences**

14:30

## PV OUTSOURCING - A LOOK INTO THE SCOPE, BENEFITS AND KEY COMPONENTS TO CONSIDER WHEN SELECTING A VENDOR

- Navigating the challenges of PV outsourcing
- The future of outsourcing
- Selecting vendors

**Rajendra Kumar Kasi**, Vice President & Global Head – Pharmacovigilance, **Glenmark Pharmaceuticals Limited**

15:00

## ALIGNING OUTSOURCING STRATEGY WITH THE OVERALL SAFETY FUNCTION STRATEGY

- Bridging Strategic Objectives: Demonstrate how a tailored outsourcing model supports the sponsor's overarching safety function goals – from compliance and global oversight to innovation, scalability, and risk mitigation.
- Operational Alignment & Governance: Outline how to integrate service provider operations with the sponsor's safety systems, processes, and metrics through robust governance, transparent communication, and flexible delivery models.
- Driving Value Beyond Cost: Highlight how strategic outsourcing goes beyond cost efficiency by enhancing agility, enabling access to global PV talent, and supporting continuous improvement in safety data quality and regulatory readiness.

**Shailesh Joshi**, Senior Director of ICSR, **Primevigilance**

15:30 Coffee & Cake Break

16:00

## IMMUNOGENICITY AND CLINICAL SAFETY CONSIDERATIONS WITH BIOLOGICS AND BIOSIMILARS

- Immunology and immunogenicity- Medical Aspects
- Immunogenicity of Biologics: General Safety & Pharmacovigilance Considerations and
- Immunogenicity of Biologics: Specific safety & Pharmacovigilance issues -Insulin, EPO, DPO, CSFs, MABs
- Immunogenicity Biosimilars : Preclinical and Clinical Comparability, Regulatory considerations
- Immunogenicity: Real world evidence and Clinical practice, patient safety considerations

**Dr. Shubhadeep Sinha**, Senior Vice-President & Medical Director, **Hetero**

16:30

## GLOBAL REGULATORY INCONSISTENCIES- VARIABILITY IN REGULATORY REQUIREMENTS ACROSS US, EU AND ROW

- Leveraging technology to meet evolving regulatory demands
- Changes in regulatory aspects as well as recent PV inspection initiated by emerging regulatory authorities
- Inconsistent reporting requirements
- Local requirements for pharmacovigilance agreements
- Differences in periodic safety update reports
- Differences in Audit and inspection expectations

### Moderator:

**Joydeep Sengupta**, GM and Global Head of Pharmacovigilance, **Curateq Biologics (Aurobindo Pharma)**

### Panelists:

**Rohan Shinde**, Assistant General Manager, **Jamp Pharmaceuticals**

**Dr Devang Patel**, Head of Global Pharmacovigilance, **Zydus**

**Dr Sridhar Yeshamaina**, Vice President and Global Head of Patient Safety and Clinical Affairs, **Anneal**

17:00 END OF DAY 1 AND CLOSING REMARKS

(SPONSORSHIP OPPORTUNITY AVAILABLE)

### 9:00 OFFICIAL START OF DAY 2 WITH OPENING REMARKS OF THE CHAIRPERSON

9:10

#### OPENING TOWNHALL DISCUSSION: EMERGING TRENDS & TECHNOLOGIES – KEY CONSIDERATIONS & CHALLENGES

Led by Chairperson:

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

Day 2 will cover topics on emerging technologies, AI & automation. This discussion allows you to introduce topics of key consideration and your challenges.

9:40

#### PROTECTING PATIENTS THROUGH RISK-BASED ASSESSMENT: THE EVOLVING ROLE OF HEALTH HAZARD ASSESSMENT IN PV

- The expanding role of Health Hazard Assessments in regulatory decision making
- Integration with real-world evidence and risk minimisation strategies

**Dr. Priya Prasad**, General Manager – Pharmacovigilance, Lupin

10:10

#### REAL TIME AI APPLICATIONS IN PHARMACOVIGILANCE

- Automated AE Detection: AI scans call transcripts, emails, EHRs, and social media in real time to capture adverse events.
- Smart Case Processing: NLP auto-extracts case details, codes MedDRA terms, and flags duplicates instantly.
- Rapid Signal Detection: ML models continuously analyze global data to identify and prioritize emerging safety signals.
- Risk Monitoring: AI integrates with EHRs, wearables, and RWD sources to track drug safety in real time.
- Regulatory Compliance: AI supports real-time narrative writing, reporting, and inspection readiness dashboards.

**Dr Sridhar Yeshamaina**, Vice President and Global Head of Patient Safety and Clinical Affairs, Amneal

10:40

#### PANEL DISCUSSION: AI/ML IN PV: EMERGING TRENDS & TECHNOLOGIES

- From hype to reality
- Signal detection
- Risk assessment
- Literature screening
- Medication compliance
- Patient centricity

Panelists:

**Dr Vaibhav Salvi**, Director and Head – Clinical Study Unit, India and South East Asia, R&D – Clinical Sciences and Operations, Sanofi

**Pooja Payal Singh**, Director Strategic Accounts, Transperfect Life Sciences

**Kishore Darisi**, SERM Associate Scientific Director, GSK

**Jamal Baig**, Multi Country Safety Head, Sanofi

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

11:10 NETWORKING BREAK

11:40

#### AUTOMATE-UP-TO-80-OF-COMPLEX-PV-REPORTS-USING-AI-DRIVEN-AUTOMATION-AND-STAY-COMPLIANT

- Strategy & best practices to achieve a high degree of automation
- Enterprise content governance, ensuring scalability while achieving compliance across global safety reports

**Amit Sood**, SVP, Enterprise Products, Quark

12:10

#### REIMAGINING ICSR FOLLOW-UP: A RISK-BASED AND AUTOMATED APPROACH TO ENHANCE PHARMACOVIGILANCE

- The Importance of ICSR Follow-Up: Addressing how robust follow-up contributes to high-quality case reports and enhanced drug safety insights
- Adopting a Risk-Based Approach: Highlighting the value of prioritizing follow-up efforts
- Automation in Follow-Up Processes: Discussing opportunities to streamline ICSR follow-up through automation and optimization using opportunities within pharmacovigilance safety systems

**Ganesh Kumar Vemula**, Vigilance Process Lead, Novartis

12:40

### ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE: REVOLUTIONIZING DRUG SAFETY OR JUST A BUZZWORD?

- Explore the current and emerging applications of AI in PV, separating hype from reality through a balanced and evidence-based lens.
- Real-world case studies
- Practical implementations, and highlight measurable outcomes where AI has improved efficiency, consistency, and accuracy in PV operations

**Chanbasha Shaik**, *Head Global Pharmacovigilance*

13:10 LUNCH BREAK

14:10

### BALANCING THE POLARITY OF QUALITY, TIME, AND VALUE IN PHARMACEUTICAL PROCUREMENT

- Strategic Relevance: It addresses core business tensions every pharma company faces
- Procurement-Centric: Procurement often sits at the intersection of these demands — managing suppliers, negotiating timelines, and ensuring compliance
- Cross-functional Impact: This topic appeals to quality, supply chain, R&D, and commercial leaders alike

**Amit Kumar**, *Global Procurement Head, Clinical Trials, R&D, Novartis*

14:40

### ANTIMICROBIAL RESISTANCE IN HEALTHCARE SETTINGS

- Escalating Threat: Rising AMR in hospitals due to inappropriate antibiotic use, limited stewardship, and infection control challenges
- Impact on Patient Safety: AMR infections prolong hospital stays, increase treatment costs, and raise mortality risks
- Strategic Response: Strengthening antimicrobial stewardship programs, infection prevention practices, and rapid diagnostics through a multidisciplinary team approach

**Dr Rahul S Kamble**, *Head of Quality, Pathology, CSSD, Infection control & Antimicrobial Stewardship, White Lotus International hospital and Research Centre*

15:10 Networking coffee break

15:40

### TOWNHALL DISCUSSION: SUMMARY OF CONFERENCE, KEY INSIGHTS, WHAT CAN WE PREPARE FOR IN 2026?

- Reflections and next steps: shaping the future of pharmacovigilance in India
- Outsourcing strategies
- Emerging technologies

**Led by Chairperson: Gurpreet Singh**, *Vice President, Managing Director Integrated Safety, IQVIA*

16:30 CLOSING REMARKS & END OF CONFERENCE

# 2025 Pharmacovigilance Summits Worldwide

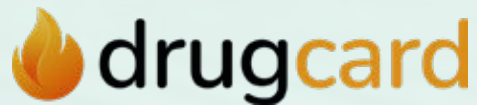


- 1** 25 - 26 February, BARCELONA  
European Drug Safety & PV Outsourcing Summit
- 2** 12 - 13 March, BOSTON  
American Drug Safety Summit 2025 - East coast
- 3** 9 - 10 April, LONDON  
10<sup>th</sup> Global Pharmacovigilance & RWE FORUM
- 4** 9 - 10 April, CHICAGO  
2<sup>nd</sup> Annual American MedTech Summit
- 5** 4 - 5 June, TORONTO  
Canadian Pharmacovigilance Management & Compliance Conference
- 6** 5 - 6 June, Basel  
2<sup>nd</sup> Annual World Drug Safety Summit
- 7** 11 - 12 June, BERLIN  
2<sup>nd</sup> Annual European MedTech Summit
- 8** 23 - 24 September, MUMBAI  
2<sup>nd</sup> Annual Global Drug Safety & PV Outsourcing Summit
- 9** 16 - 17 October, Boston  
2<sup>nd</sup> American Drug Safety Summit 2025 - East Coast
- 10** 9 - 10 December, SAN DIEGO  
American Drug Safety Summit 2025 - Westcoast

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# Sponsorship



Additional sponsorship opportunities are available for those who wish to further customize their involvement.

## Exhibiting

With a large and senior audience and decision makers, thoroughly selected, exhibiting at any Summit at 2025 FoP SUMMIT WORLD is a popular sponsorship option with great value for solution providers.

Sponsorship includes

- Selected Summit Three Access Passes
- Exhibition space
- Helping to prearrange face to face meetings with selected participants

## Dinner Sponsorship

2025 FoP SUMMIT WORLD TOUR will host a series of dinners These dinners bring together thoughtfully selected groups of 15-20 peers from established pharma, biotech, healthcare, and medtech companies. The dines start with a 30-minute networking reception followed by a 60-minute seated dinner, with the option for participants to remain afterward to continue networking.

- Selected Summit Three Access Passes
- 30-minute reception, and 60 minute seated dinner

## Speaking

Limited speaking opportunities are available for our sponsoring partners to demonstrate the expertise of their organization. Be sure to ask about these early so we can ensure your presentation flows seamlessly with the overall content. Speaking sponsorships has several options – keynote presentations, case study presentations, expert presentations, panel discussions, workshops, or roundtable leadership. Speaking opportunities are available for experts in the field of Drug safety specialists, QPPVs, Safety Heads, C-level pharmaceutical and biotech executives, hospital management, clinicians, epidemiologists, pharmacologists, Project and Portfolio Management, Contract Management, Consultancy, CROs, Data Management, Artificial Intelligence, Robotics and Digital Innovation experts

# Contact us

Updated: 17 September, 2025  
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## Speaking:



**Jan Cizek**

jan.cizek@whysummits.com

## Sponsoring:



**Lubos Kusy**

lubos@whysummits.com

## Sponsoring:



**Rakesh Multani**

rakesh@whysummits.com

### Disclaimer:

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