WHY? SUMMITS

**Updated:** 8 April, 2025
for the latest programe update, please download agenda on conference website

10TH ANNUAL GLOBAL

# PHARMACOVIGILANCE & RWE Forum

Part of Pharmacovigilance World Tour

**Hilton London Olympia, 380 Kensington High St, London W14 8NL, United Kingdom**

**9 - 10 April 2025**

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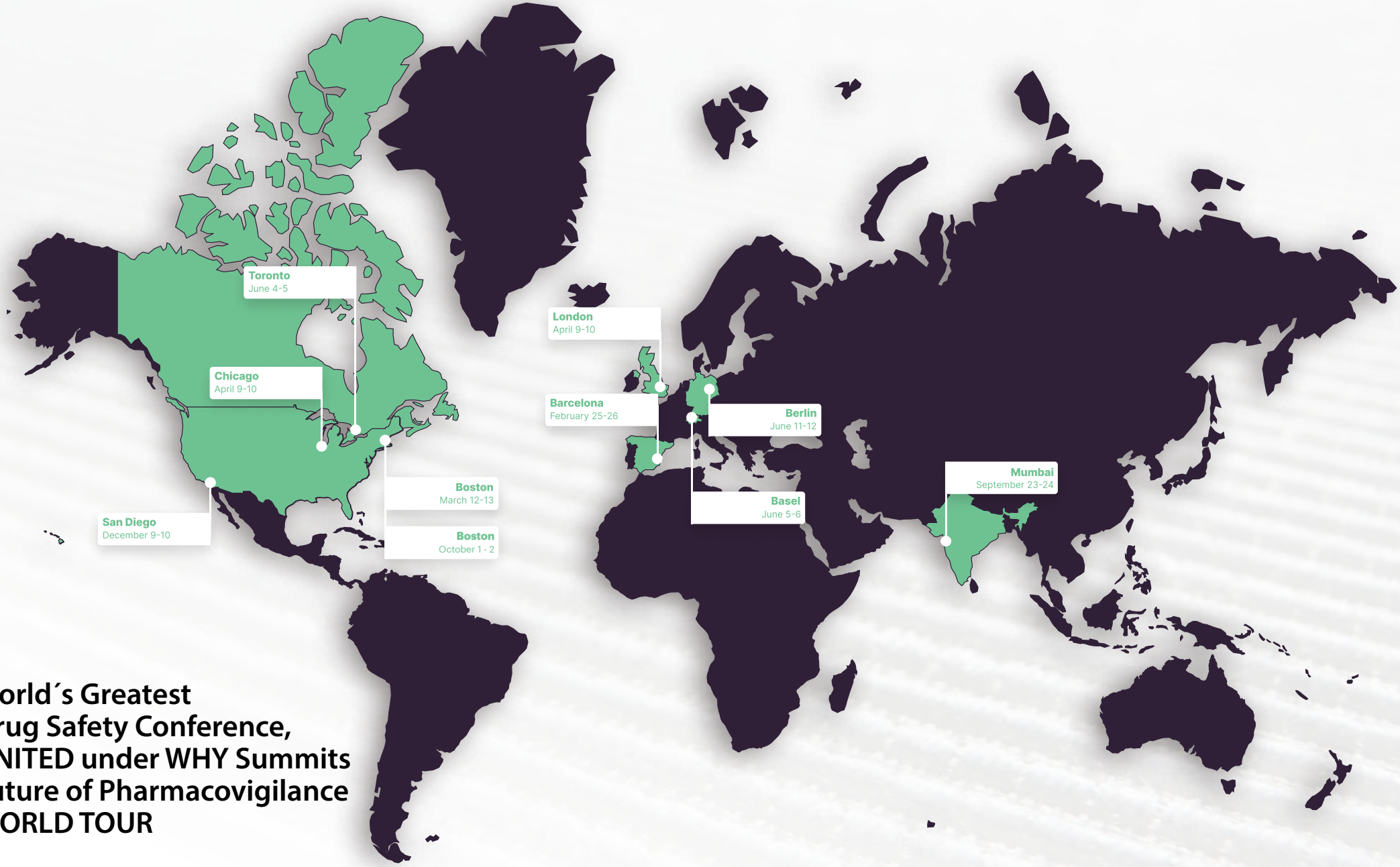
# 2025 Pharmacovigilance Summits Worldwide




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

# Future of Pharmacovigilance

## Our most prestigious European event, starting off our 2025 PV World Tour

**Meet**

Europe's 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

# Always ask WHY?

Our London concentrated knowledge-focused meeting will be focusing on topics of:

**2025 outlook, trends and upcoming challenges**

**RWE and regulatory decision-making updates**

**Challenges for individualized patient outcomes and targeted therapies**

**Implementing real-time RWE surveillance with legacy systems**

**Ensuring data integrity and accuracy in safety reporting**

**Strategies for RWE into existing PV frameworks**

**Detecting subtle safety signals**

**Automation for heightened efficiency, precision, and compliance in risk management**

**Global regulatory and compliance harmonization**

# You will spend your time with:

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

**Souhail Debaghi**
Director of Sales
**TriNetX**
★★★★★

"My highlights were hearing from the industry PV & Safety leaders, including: the brilliant panel with IPSEN's Pav Rishiraj, Sanofi's John Solomon MD and CSL's Rishi C. who spoke about the importance of PV leaders to educate their colleagues and leadership on the "What" they do, and "Why" they do it, so the role of patient safety is appreciated beyond simply the "Police" of Pharma."

**Sanjeev Srivastav**
Signal Management Lead
**BioNTech**
★★★★★

"I had the pleasure of attending an insightful panel discussion featuring Pav Rishiraj, Gurpreet Singh, John Solomon MD, and Rishi C.! The pragmatic discussions truly reflected ground realities, and the practical tips provided were invaluable. Kudos to the organiser Tomas Rendek Why Summits for the excellent choice of topics and for bringing together the experts to address the real-world challenges in utilizing real-world evidence for patient safety."

**Lewis Atkinson**
Director of Business Development for PV Drug Safety Technology
**IQVIA**
★★★★★

"Finishing off Day 2 with my IQVIA colleague Gurpreet Singh taking part in an open plenary discussion about "collaborations with HCP's and utilising digital tools". I have thoroughly enjoyed the past 2 days of networking with my colleagues and industry professionals. Thank you to Why Summits & Tomas Rendek for wonderful organisation and to Erika Barbarosie for chairing the event! I look forward to Basel later in the year!"

**Cláudia Meneses**
Senior Pharmacovigilance Officer
**Sanofi**
★★★★★

"Thanks to the 9th Global Pharmacovigilance & RWE Forum speakers, particularly Michael von Forstner, Alexandru Barbarosie, MD, Arun Ravindran, MD, and Karen Cheng, for sharing their knowledge and experience. It was a great first Pharmacovigilance conference and a good chance to meet more like-minded people in the industry."

**Erika Barbarosie**
Associate Director PV Compliance
**Gilead Sciences**
★★★★★

"Absolutely a blast, thank you Tomas, Zuzana and Why Summits! There are a vast variety of topics, interesting and exicting conversations, insightful presentations about hashtag#patientsafety, hashtag#compliance, hashtag#signalmanagement and more. I'm humbled that I can be a part of this - unmatching educational experience."

**Nick Nikberg**
Senior Safety Specialist
**AstraZeneca**
★★★★★

"What an excellent 2-day event connecting with friends and industry colleagues, old and new. There was plenty to digest, lots of learnings and take home messages whilst we shared best practices. Looking forward to the next one!"

# Meet the first onboarded speakers to 2025 edition:

**Andrea De Iacovo**
Global Head of Pharmacovigilance
**Besins Healthcare**

**Mark Cawley**
Associate Director, Research Procurement (Reg Affairs, PV & Med Affairs)
**Jazz Pharmaceuticals**

**Sarika Paradkar**
Global Safety Physician - Early Phase Trials
**Ipsen**

**Teresa Saragoca**
Technical & Regulatory Affairs Director
**Italfarmaco**

**Muhammad Memon**
Chief Medical Officer
**Complement Therapeutics**

**Amer Alghabban**
R&D Quality Regulatory Authority Inspection Management
**Bristol Myers Squibb**

In the Chair

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

**Michael von Forstner**
Head of Safety Science
**SOBI**

**Pratiksha Dokhe**
Patient Safety Physician

**Amit Jadhav**
Director Global Patient Safety
**Regeneron**

**Vijay Kara**
Safety and Quantitative Innovation Director
**GSK**

**Nick Nikberg**
Associate Scientific Director
**GSK**

**John Solomon**
Head of Pharmacovigilance - UK & Ireland
**Sanofi**

# Meet the first onboarded speakers to 2025 edition:

**Neha Verma**
Manager – Pharmacovigilance Quality Management
**Regeneron**

**Rishi Chopra**
Executive Director, Head of International Pharmacovigilance (IPV) & Global PV Operations
**CSL Behring**

**Shikta Das**
Real World Evidence Scientific Lead, Oncology
**AstraZeneca**

**Vijay Singh**
Associate Director (Signal Management SME)- Patient Safety
**Gilead**

**Nicole Baker**
CEO & Founder
**BioLogit**

**Emerson Welch**
VP Global Marketing
**Quark Software**

**Sanjeev Srivastav**
Signal Management Lead
**BioNTech**

**Tasi (Anastasia) Lampropoulou**
Director, Global Integrated Evidence Planning
**Novartis**

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

**Fabio De Gregorio**
Vice President & Head of Drug Safety
**Shionogi Europe**

**Dr Adrian Rabe**
Head of the RWE CoE
**Boehringer Ingelheim**
& Visiting Professor, Primary Care and Public Health
**Imperial College London**

**Zina Sadeq**
Director, Regional PV and Alliance Management, UK QPPV
**Amicus Therapeutics**

**Stephanie-Jayne Jones**
Chief Medical Officer
**Pharmora Limited**

# Agenda

18:00

**EVENING BEFORE SUMMIT - MEET & GREET**

Informal meeting in the Lobby of the hotel for all attendees coming to the conference the night before. Register and receive your badge in advance, and enjoy a pre-event meet and greet with a few attendees before we kick-off Day 1.

# Day1

8:30 MORNING REGISTRATION AND EARLY BIRDS NETWORKING COFFEE

9:00 OFFICIAL START OF 10TH ANNUAL PHARMACOVIGILANCE & RWE FORUM WITH OPENING REMARKS OF THE CHAIRPERSON

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

9:10 NEXT-SEAT- MEET & GREET

9:20 **THE IMPACT OF RECENT EMA, FDA AND CIOMS GUIDANCE ON LIFECYCLE PV PLANNING**

- How do GVP XVI Rev3, FDA REMS Logic, and CIOMS XII enhance the need for proactive RWE generation
- Global harmonization of approaches throughout the product lifecycle
- Potential implications for PV and PEpi professionals

**Michael Forstner,** *Head of Safety Science,* **SOBI**

9:50 **EXPLORING RISK MANAGEMENT, MINIMISATION MEASURES AND EFFECTIVENESS**

**Nick Nikberg,** *Associate Scientific Director,* **GSK**

10:20 **OPENING ROUND-TABLE DISCUSSIONS:** NAVIGATING THE FUTURE OF PHARMACOVIGILANCE

- What are the main challenges that we need to focus on?
- Key trends and technologies

**Round-table Leader: Gurpreet Singh,** *Vice President, Managing Director Integrated Safety Data Sciences, Safety and Medical,* **IQVIA**

10:50 MORNING BREAK: COFFEE, CAKE & NETWORKING

11:20 **KEYNOTE:** AI APPLICATIONS FOR SAFER DRUGS, SAFER CLINICAL PRACTICES AND LOOKING INTO NEW AI REGULATION

**Teresa Saragoca,** *Technical & Regulatory Affairs Director,* **Italfarmco**

11:50 **ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING IN PV:** PRACTICAL CONSIDERATIONS

**Vijay Kara,** *Safety and Quantitative Innovation Director,* **GSK**

12:20 **AI IN PHARMACOVIGILANCE:** STREAMLINING LOCAL AND GLOBAL LITERATURE SURVEILLANCE

- The challenges of Local Literature in Pharmacovigilance
- How AI is Transforming Literature Surveillance
- Biologit's AI Approach
- Regulatory Considerations and AI Adoption

**Nicole Baker,** *CEO,* **BioLogit**

12:50 LUNCH BREAK

13:50 **PANEL DISCUSSION:** HOW RWE IS TRANSFORMING PV

- How RWE can ensure patient-centricity in a changing legal and regulatory landscape
- How RWE is changing the landscape of safety signal detection
- How automation can enhance compliance

**Panel leader: Sanjeev Srivastav,** *Signal Management Lead,* **BioNTech**
**Panelists:**
**Dr Adrian Rabe,** *Head of the RWE CoE,* **Boehringer Ingelheim**
**Shikta Das,** *Real World Evidence Scientific Lead, Oncology,* **AstraZeneca**
**Gurpreet Singh,** *Vice President, Managing Director Integrated Safety Data Sciences, Safety and Medical,* **IQVIA**

14:30 **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 (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**

15:00 **PRACTICAL ASPECTS OF SIGNAL DETECTION IN EARLY PHASE CLINICAL TRIALS**

- How do the teams work together in Early Phase to conduct signal surveillance activities
- Challenges of working in EP Vs Late Phase clinical trials

**Amit Jadhav,** *Director Global Patient Safety,* **Regeneron**

15:30 COFFEE & CAKE BREAK

# Day1

16:00 **PANEL DISCUSSION:** PV RISK MANAGEMENT

- Interactions between medical affairs and pharmacovigilance to enhance effectiveness of the risk management strategy
- Enhancing data effectiveness and risk management
- Regulatory compliance & risk management
- Utilization of AI – progress toward patient safety and risk minimization

**Panel leader:** **Gurpreet Singh,** *Vice President, Managing Director Integrated Safety Data Sciences, Safety and Medical,* **IQVIA**

**Panelists:**

**John Solomon,** *Head of Pharmacovigilance - UK & Ireland,* **Sanofi**

**Nick Nikberg,** *Associate Scientific Director,* **GSK**

**Zina Sadeq,** *Director, Regional PV and Alliance Management, UK QPPV,* **Amicus Therapeutics**

**Stephanie-Jayne Jones,** *Chief Medical Officer,* **Pharmora Limited**

17:00 END OF DAY 1 & CLOSING REMARKS FROM THE CHAIRPERSON

# Day2

8:50 OPENING REMARKS FROM CHAIRPERSON

9:00 **ROUND-TABLE DISCUSSION:** KEY CHALLENGES IN PV: WHAT'S STOPPING YOU FROM BRINGING VALUE TO YOUR ORGANISATION?
**Round-Table Leader: Stephanie-Jayne Jones,** *Chief Medical Officer,* **Pharmora Limited**

9:30 **FUTURE-PROOFING CLINICAL TRIALS:** STRATEGIC APPROACHES TO GCP INSPECTION READINESS AND MANAGEMENT
- Understand how proactive inspection preparation benefits clinical study teams by reducing operational burdens.
- Gain insights into QA strategies that improve trial quality and data credibility.
- How study teams can effectively contribute to inspection readiness through better documentation and process alignment.

**Amer Alghabban,** *R&D Quality Regulatory Authority Inspection Management,* **Bristol Myers Squibb**

10:00 **AFFILIATE PHARMACOVIGILANCE:** A CASE STUDY IN TRANSFORMATION
- The differing models and the merits and disadvantages
- Creating a harmonized organisational design for Affiliate Pharmacovigilance
- The pitfalls and watchouts in managing the transformation

**Rishi Chopra,** *Executive Director, Head of International Pharmacovigilance (IPV) & Global PV Operations,* **CSL BEHRING**

10:30 NETWORKING BREAK

11:00 **OPPORTUNITIES AND CHALLENGES OF A GLOBAL PHARMACOVIGILANCE SYSTEM**
- Collaboration at the interface: Affiliates - Partners - Service Providers
- Management of Safety Data Exchange Agreement and other contracts
- Inspection readiness across the Globe

**Andrea De Iacovo,** *Global Head of Pharmacovigilance,* **Besins Healthcare**

11:30 **HOW TO SELECT THE RIGHT VENDOR FOR YOUR PROJECT – AND HOW YOUR PROCUREMENT TEAM CAN HELP YOU**
- The most important step for any outsourcing project is vendor selection: this is especially the case for PV and RWE activities
- If you get this right, most of the challenges on your project can be avoided – because they'll never happen
- But pick the wrong supplier or CRO, and your time will be spent fighting fires
- The key steps for vendor selection – and how procurement can assist
- Vendor oversight during a project

**Mark Cawley,** *Associate Director, Research Procurement (Reg Affairs, PV & Med Affairs),* **Jazz Pharmaceuticals**

12:30 **INTEGRATED EVIDENCE PLANNING**

**Tasi Lampropoulou,** *Director, Global Integrated Evidence Planning,* **Novartis**

13:00 LUNCH BREAK

14:00 **LEVERAGING GENERATIVE AI IN QUALITY MANAGEMENT:** ENHANCING EFFICIENCY
- Role of generative AI in PV Quality data/trend analysis
- Use prompts with relevant datasets or information in generating relevant responses using generative AI.
- Share the use case at a high level

**Neha Verma,** *Manager – Pharmacovigilance Quality Management,* **Regeneron**

14:30 **FROM DATA TO DECISIONS:** LEVERAGING RWE AND AI

**Shikta Das,** *Real World Evidence Scientific Lead, Oncology,* **AstraZeneca**

15:00 **PANEL DISCUSSION:** OUTSOURCING & PV STRATEGIES ALIGNMENT
- Hot off the press: FDA rejected trials conducted by a CRO: what impact could this have for us in selecting a pharmacovigilance vendor?
- What do you think will be the impact of the FDA RIF (Reduction in Force) on Patient Safety?
- Top tips for selecting the right vendor

15:45 NETWORKING COFFEE BREAK

16:10 **CLOSING ROUND-TABLE DISCUSSION:** REFLECTIONS AND NEXT STEPS: SHAPING THE FUTURE OF PHARMACOVIGILANCE
- Wrap-up and outline actionable steps for integrating RWE into future pharmacovigilance strategies.
- An open plenary discussion, with chairperson introducing the most interesting & unanswered questions. The conference will end as a free interactive networking and discussion setting goals for 2025.

**Round-table Leader: Gurpreet Singh,** *Vice President, Managing Director Integrated Safety Data Sciences, Safety and Medical,* **IQVIA**

17:00 CLOSING REMARKS FROM WHY SUMMITS AND THE CHAIRPERSON

# 2025 World tour at a glance

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
   10th Global Pharmacovigilance & RWE FORUM
4. 9 - 10 April, CHICAGO
   2nd Annual American MedTech Summit
5. 4 - 5 June, TORONTO
   Canadian Pharmacovigilance Management & Compliance Conference
6. 5 - 6 June, Basel
   2nd Annual World Drug Safety Summit
7. 11 - 12 June, BERLIN
   2nd Annual European MedTech Summit
8. 23 - 24 September, MUMBAI
   2nd Annual Global Drug Safety & PV Outsourcing Summit
9. 9 - 10 December, SAN DIEGO
   American Drug Safety Summit 2025 - Westcoast

# Our Past Partners

WHY? SUMMITS

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Quark

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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:** 8 April, 2025
for the latest programe update, please download agenda on conference website

**SPEAKING:**

**Jan Cizek**
jan.cizek@whysummits.com

**ATTENDING AND SPONSORING:**

**Rakesh Multani**
rakesh@whysummits.com

**ATTENDING AND SPONSORING:**

**Lubos Kusy**
lubos@whysummits.com

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