WHY? SUMMITS

Updated: 3 June, 2025
for the latest programe update, please download agenda on conference website

June 5 - 6
2025

FUTURE OF PHARMACOVIGILANCE WORLD TOUR
WORLD DRUG SAFETY SUMMIT BASEL

World's greatest minds in drug safety, pharmacovigilance, data analysis, reporting, government policy, and innovative technology.

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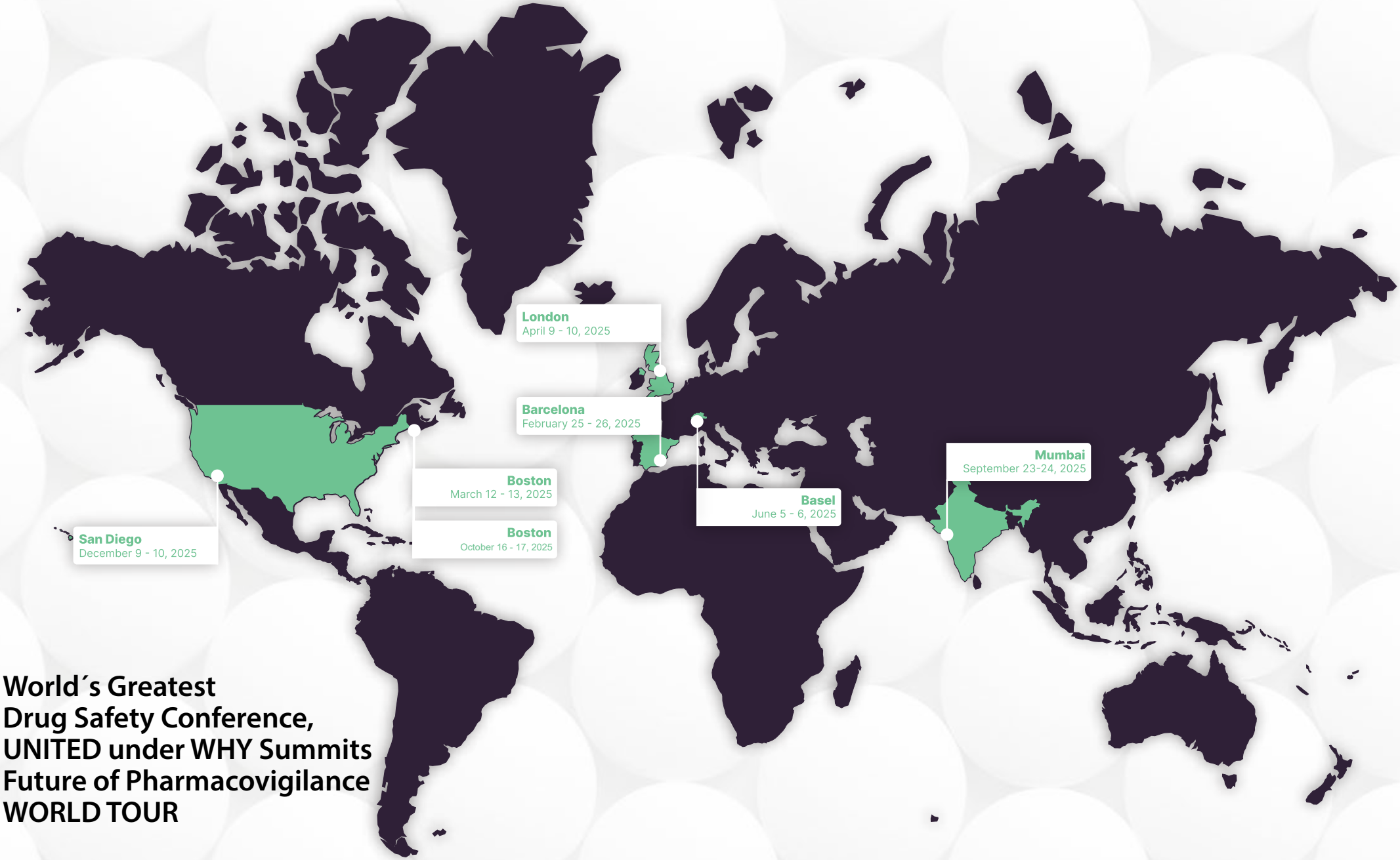
Authorities joining the summit

swissmedic

2025 Pharmacovigilance Summits Worldwide



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

Future of Pharmacovigilance

WHY? SUMMITS

Join our most prestigious European PV event, as part of our 2025 PV World Tour

Meet

crème de la crème of Drug Safety professionals from our 2023 world tour

Learn

about the most important issues addressed during the world tour

Discuss

the vision for 2024 and further

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?

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 Basel concentrated knowledge-focused meeting, is assembled in 8 blocks focusing on:

Real world implementation of Patient-centric Drug Safety strategies

Low-end digital disruptions in PV: improving lives while cutting costs

Advancements in Benefit-Risk assessment and aRMMs

Post Trial Access and Clinical Safety

Multidepartment collaboration towards better safety and commercial outcomes

Regulatory Affairs in Drug Safety

Innovative approach in signal detection & reporting automation

Role of Pharmacovigilance in data-driven pharmaceutical business

Comprehensive compliance updates in European Pharmaceutical Safety

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

"Unlike some other similar events, I found relevance in every session within your conference. The content was neither too simplistic nor too advanced. The participants and presenters provided a diverse view of the issues that are present for most in this industry."

Christine Clearwater, Manager, Safety Operations and Vendor Management, Baxter, Global Patient Safety

"Great dialogue on key issues. Everyone shared truthful insight and did not hold back, even on negative experiences."

Sameer Thapar, Assistant Professor & Advisor, Drug Safety and Pharmacovigilance, Rutgers University

"Loved it. It was very practical and provided valuable insight into practical methods that are actionable for patient safety."

Daniel Naranjo, Global Safety Lead, Global Patient Safety Evaluation, Takeda

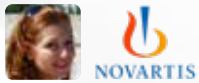
Industry Pioneers Attending From

Meet the first onboarded speakers to 2025 edition:

Sanjeev Srivastav
Signal Management Lead
BionTech

Michael von Forstner
Head of Safety Science
SOBI

Petros Mavrogenis
Head Vigilance Process Excellence
Novartis

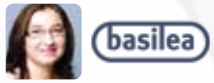


Luvanka Hanxhari
Senior Manager Agregate Reports & Risk Management – RMP
Novartis

Adriano Galati
Digital Safety Director Pharmacovigilance & Scientific Development
Roche

Marija Simic Koumoutsaris
Director Medical Safety
Sandoz

Jost Leemhuis
Patient Safety Partner
Roche



Elena Radu
Senior Drug Safety Physician
Basilea Pharmaceutica International Ltd.

Marjan Dzeparoski
PV Manager & University lecturer
Bionika Pharmaceuticals/UGD

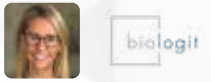
Mircea Ciuca
Global Head Medical Safety
Organon

Monika Zych
PS Director, CEEI&META, UKI & Nordics, DACH
Baxter

Remco M. Diab
Sr. Dir. Lead Global Safety Officer Immunology & Inflammation
Sanofi

Etienne Raemy
Head of Pharmacovigilance
Debiopharm Research & Manufacturing

Abdul Rahim
Founder & Director
Alwis Group



Jean Redmond
COO
Biologit

Sabine Poltermann
Head of Country Patient Safety Switzerland
BMS

Marianne Soergel-Ahovi
Head Drug Safety
Molecular Partners

Nurana Aghayeva
Head of Quality and Pharmacovigilance Department
Zeytun Pharmaceuticals LLC

Agenda

Day1

8:30 MORNING REGISTRATION

9:00 OFFICIAL START OF WORLD DRUG SAFETY SUMMIT WITH OPENING REMARKS

9:10 NEXT-SEAT-MEET & GREET
Get to know the people seated at your table

9:20 **STRATEGIC ROLE OF PHARMACOVIGILANCE IN DATA-DRIVEN** PHARMACEUTICAL INDUSTRY
- Highlighting the critical role of pharmacovigilance in leveraging data, namely RWE & RWD to drive innovation and ensure drug safety in the pharmaceutical industry

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

9:50 **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

Jean Redmond, *COO,* **Biologit**

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

10:50 MORNING BREAK: COFFEE & NETWORKING

11:20 **MOVING BEYOND COMPLEXITY:** CLARITY AND COLLABORATION IN SAFETY PRACTICES
- Addressing complexity in safety through role and responsibility approaches
- Shifting mindsets to reduce complexity and create an effective safety culture
- Embracing a unified approach to break down silos and enhance collaboration
- Emphasizing simplicity and focusing on the "why" to drive strategic thinking and innovation
- Adopting streamlined practices by reassessing local ways of working and legal requirement

Sabine Poltermann, *Head of Country Patient Safety Switzerland,* **BMS**

18:30
EVENING BEFORE SUMMIT - MEET & GREET
Informal meeting in the Lobby of the hotel for all attendees coming to the conference the night before, to register and receive your badge in advance

11:50 **CASE STUDY:** DOES REPEATED FOLLOW-UP PRODUCE BETTER QUALITY SAFETY DATA? EFFORT VS REWARD
- An analysis of follow-up attempts for adverse event reports was conducted to describe the characteristics of a risk-based follow-up for Individual Case Safety Reports (ICSR)

Petros Mavrogenis, *Global Head Vigilance Process Excellence,* **Novartis**

12:20 **PV REGULATORY INTELLIGENCE - AGGREGATE REPORTS AND ICSR REPORTING AND BEYOND**
- PV Regulatory Intelligence – setting the stage
- Main steps of PV Regulatory Intelligence process
- Challenges
- Oversight
- Future pace
- Case study

Elena Radu, *Senior Drug Safety Physician,* **Basilea Pharmaceutica International Ltd., Allschwil**

12:50 LUNCH BREAK

13:50 **PANEL DISCUSSION:** CROSS COLLABATION & ESTABLISHING A SAFETY CULTURE
- Fostering a culture of collaboration
- Making safety more visible
- Communication culture for efficiencies
- Managing stakeholder expectations

Remco Diab, *Sr. Dir. Lead Global Safety Officer Immunology & Inflammation,* **Sanofi**
Etienne Raemy, *Head of Pharmacovigilance,* **Debiopharm Research & Manufacturing**
Marija Simic Koumoutsaris, *Director Medical Safety Team Lead, Global Patient Safety,* **Sandoz**

14:30 **CASE STUDY:** LOW-END DIGITAL DISRUPTIONS IN ARMMS: IMPROVING ACCESS TO SAFETY INFORMATION
- So-called low-end digital disruption sums up innovations are transforming pharmacovigilance in era of ever decreasing budgets.
- Simple real world use case demonstration on ways these disruptions enhance patient outcomes while reducing operational costs.

Luvanka Hanxhari, *Senior Manager Aggregate Reports & Risk Management – RMP,* **Novartis**

Day1

15:00 **LEVERAGING DIGITAL TECHNOLOGY TO MANAGE THE RISK OF PREGNANCY**
Adriano Galati, *Digital Safety Director Pharmacovigilance & Scientific Development,* **Roche**

15:30 COFFEE BREAK & NETWORKING

16:00 **COLLABORATIVE DIGITAL DATA SPACES TO INFORM PATIENTS AT RISK**
- A German collaborative data space

Jost Leemhuis, *Patient Safety Partner,* **Roche**

16:30 **ROUND-TABLE DISCUSSION:** PATIENT-CENTRIC PHARMACOVIGILANCE: ENGAGING PATIENTS IN DRUG SAFETY

17:00 END OF DAY 1 – CLOSING REMARKS FROM CHAIRPERSON AND WHYSUMMITS

Day2

8:30 MORNING REGISTRATION AND EARLY BIRDS NETWORKING COFFEE

9:00 OFFICIAL START OF WORLD DRUG SAFETY SUMMIT WITH OPENING REMARKS FROM WHY SUMMITS AND THEIR CHAIRPERSON

9:10 **ROUND-TABLE DISCUSSION:** DIGITALIZATION OF PV
- Where can we see the biggest impact of digital solutions in PV?
- Practical applications of AI
- Are we digitally ready? The real state of PV digital maturity in 2025

9:40 **LEGAL REQUIREMENTS FOR PSSF AND COMPARISON TO PSMF**
- PSMF vs PSSF
- Creating local PV system description
- Adjusting PSSF to local business models

Monika Zych, *PS Director, CEEI&META, UKI & Nordics, DACH,* **Baxter**

10:10 **CASE STUDY:** RESERVED FOR ALWIS GROUP
Abdul Rahim, *Founder & Director,* **Alwis Group**

10:40 COFFEE BREAK & NETWORKING

11:10 **SIGNAL MANAGEMENT:** LET'S GET REAL!
- **Signal Management is Core to Pharmacovigilance:** It plays a central role in identifying, assessing, and acting on safety signals to protect patients effectively.
- **Embrace of New Technologies:** The integration of AI, big data analytics, wearables, and predictive modeling can dramatically enhance the speed and accuracy of signal detection.
- **Real-time Monitoring is the Future:** Continuous, real-time data from clinical trials, post-marketing surveillance, and wearables can revolutionize safety monitoring.
- **Need for Regulatory Harmonization and Standardization:** Variability across regulators, academia, and industry calls for unified methods and global standards like READUS-PV.
- **Call for a PV Mindset Shift:** The presentation urges a redefinition of pharmacovigilance practices—moving from reactive to proactive, integrated, and tech-enabled signal and risk management.

Mircea Ciuca, *Global Head Medical Safety,* **Organon**

11:40 **RISK COMMUNICATION**
- Ensuring steps in ensuring relevant, clear, accurate and consistent
- Emphasis on DHPC
- How we do so in the Balkan region

Marjan Dzeparoski, *PV Manager & University Lecturer,* **Bionika Pharmaceuticals/UGD**

12:10 **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

Luvanka Hanxhari, *Senior Manager Aggregate Reports & Risk Management – RMP,* **Novartis**
Mircea Ciuca, *Global Head Medical Safety,* **Organon**
Marjan Dzeparoski, *RA & PhV Manager,* **Bionika Pharmaceuticals/UGD**
Nurana Aghayeva, *Head of Quality and Pharmacovigilance Department,* **Zeytun Pharmaceuticals LLC**
Marianne Soergel, *Head Drug Safety,* **Molecular Partners**

12:40 LUNCH BREAK

13:40 **HOW MUCH CAN AI CONTROL DRUG SAFETY DOCUMENTATION?**
- The capabilities and limits of AI in creating highly regulated documents
- The more significant issue of complex data integration
- Automation and on-demand document generation are the real goals

Emerson Welch, *VP Global Marketing,* **Quark**

14:10 **PANEL DISCUSSION:** AI IN PHARMACOVIGILANCE: HYPE VS. REALITY IN SAFETY INTELLIGENCE AND DECISION-MAKING
- Where Are We Actually Seeing Value?
- Regulatory & Ethical Alignment: Navigating EMA expectations, ensuring explainability, and addressing data privacy and bias in AI tools.
- Operational Integration: Real-world use cases of AI in ICSR processing, signal detection, and literature monitoring—what's working and what's not.

Panelists:
Mircea Ciuca, *Global Head Medical Safety,* **Organon**
Michael Forstner, *Head of Safety Science,* **SOBI**
Jean Redmond, *COO,* **Biologit**
Emerson Welch, *VP Global Marketing,* **Quark**

14:50 **ADVANCEMENTS IN VACCINE SAFETY:** LANDSCAPE FOR PERSONALISED VACCINE
- Evaluating the current state of patient and safety-centric practices in major pharmaceutical companies.
- Identifying opportunities for enhancing patient engagement and safety protocols in rapidly advancing landscape of personalized vaccines.

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

15:20 COFFEE & NETWORKING BREAK

15:50 **ROUND-TABLE DISCUSSION:** SETTING VISIONS FOR 2026
- Workforce skills gap: preparing PV professionals for tomorrow
- How can PV keep up with complex products whose safety profiles are less predictable and more individualized?
- Predictions for 2026
- Lessons from 2025

16:20 CLOSING REMARKS FROM CHAIRPERSON AND WHY SUMMITS

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. 16 - 17 October, BOSTON
   2nd American Drug Safety Summit 2025 - East coast
10. 9 - 10 December, SAN DIEGO
    3rd American Drug Safety Summit & AI 2025 - Westcoast

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PHARMORA

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 2024 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

2024 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

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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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