



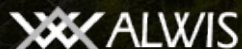
Updated: 25 May, 2025
for the latest programme update,
please download agenda on
conference website

June 5 - 6
2025

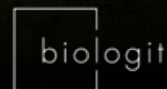
FUTURE OF PHARMACOVIGILANCE WORLD TOUR WORLD DRUG SAFETY SUMMIT BASEL

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

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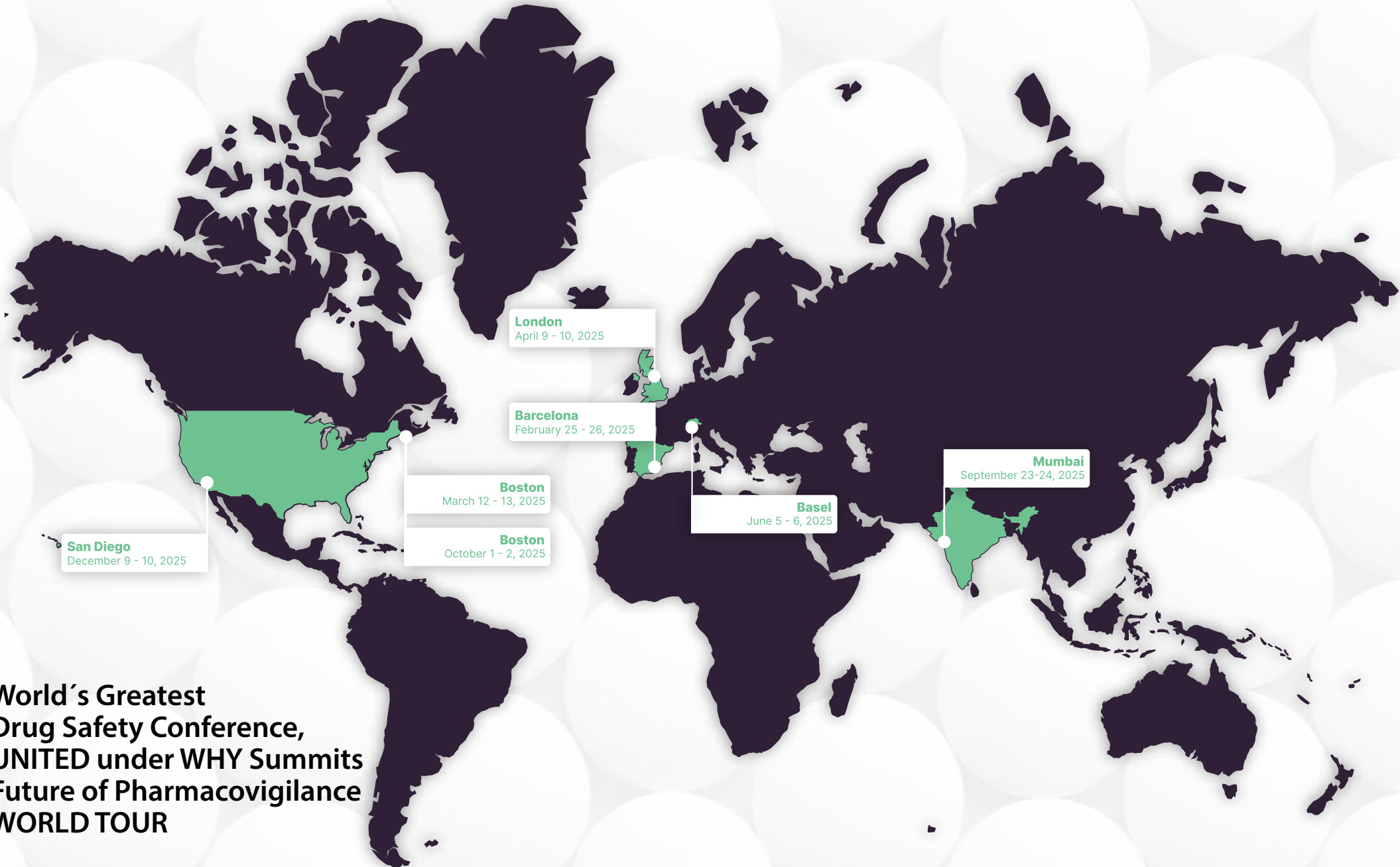
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joining the summit



2025 Pharmacovigilance Summits Worldwide



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

"ALWAYS BE CURIOUS"

WWW.WHYSUMMITS.COM

Future of Pharmacovigilance



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 BE CURIOUS"

WWW.WHYSUMMITS.COM

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



Santanu Mukhopadhyay
Head of Global Patient
Safety
Merck



Adriano Galati
Digital Safety Director
Pharmacovigilance &
Scientific Development
Roche



Alejandra Padovani
Medical Safety Director
Gene Therapy
Uniqure



Gurpreet Singh
Vice president Integrated Safety
IQVIA



**Marija Simic
Koumoutsaris**
Director Medical Safety
Sandoz



Jost Leemhuis
Patient Safety Partner
Roche



Elena Radu
Senior Drug Safety Physician
Basilea Pharmaceutica
International Ltd.



Marjan Dzeperoski
PV Manager & University lecturer
Bionika



Mircea Ciuca
Global Head Medical Safety
Organon



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



Catarina Martins
Group Head Global Risk
Management Plans
Novartis



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



Nicole Baker
CEO
Biogit

Agenda

Day 1

- 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** NEXT-SEAT-MEET & GREET
Get to know the people seated at your table
- 9:20** **KEYNOTE:** 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** **RESERVED PRESENTATION:** FUTURE OF PHARMACOVIGILANCE
IQVIA
- 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: TBA
- 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 COLLABORATION & 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**
Catarina Martins, Group Head Global Risk Management Plans, **Novartis**
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 **DIGITAL SOLUTIONS IN PV**
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: KEY FOCUS AREAS AND CHALLENGES IN SUMMARY OF DAY 1**

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:** TOPIC TBA BY ROUND-TABLE LEADER
- 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**
- 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 Dzeperoski**, *PV Manager & University Lecturer, Bionika*
- 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*
-
- 12:40 LUNCH BREAK
- 13:40 **RESERVED FOR BIOLOGIT**
- Nicole Baker**, *CEO, Biologit*

- 14:10 **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*
- 14:40 **PANEL DISCUSSION:** AI IN PHARMACOVIGILANCE: HYPE VS. REALITY IN SAFETY INTELLIGENCE AND DECISION-MAKING
- Where Are We Actually Seeing Value?
 - Hurdles Of Trusting AI - Case-Study
 - What Are The Main Challenges We Need To Consider?
-
- 15:10 COFFEE & NETWORKING BREAK
- 15:40 **ROUND-TABLE DISCUSSION:** SETTING VISIONS FOR 2026
-
- 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** 1 - 2 October, BOSTON
2nd American Drug Safety Summit 2025 - East coast
 - 10** 9 - 10 December, SAN DIEGO
3rd American Drug Safety Summit & AI 2025 - Westcoast

Our Valued Partners, Past and Present



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

Updated: 25 May, 2025

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



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ATTENDING AND SPONSORING:

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