WHY? SUMMITS

Updated: 5 May, 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.

Gold Sponsor: ALWIS

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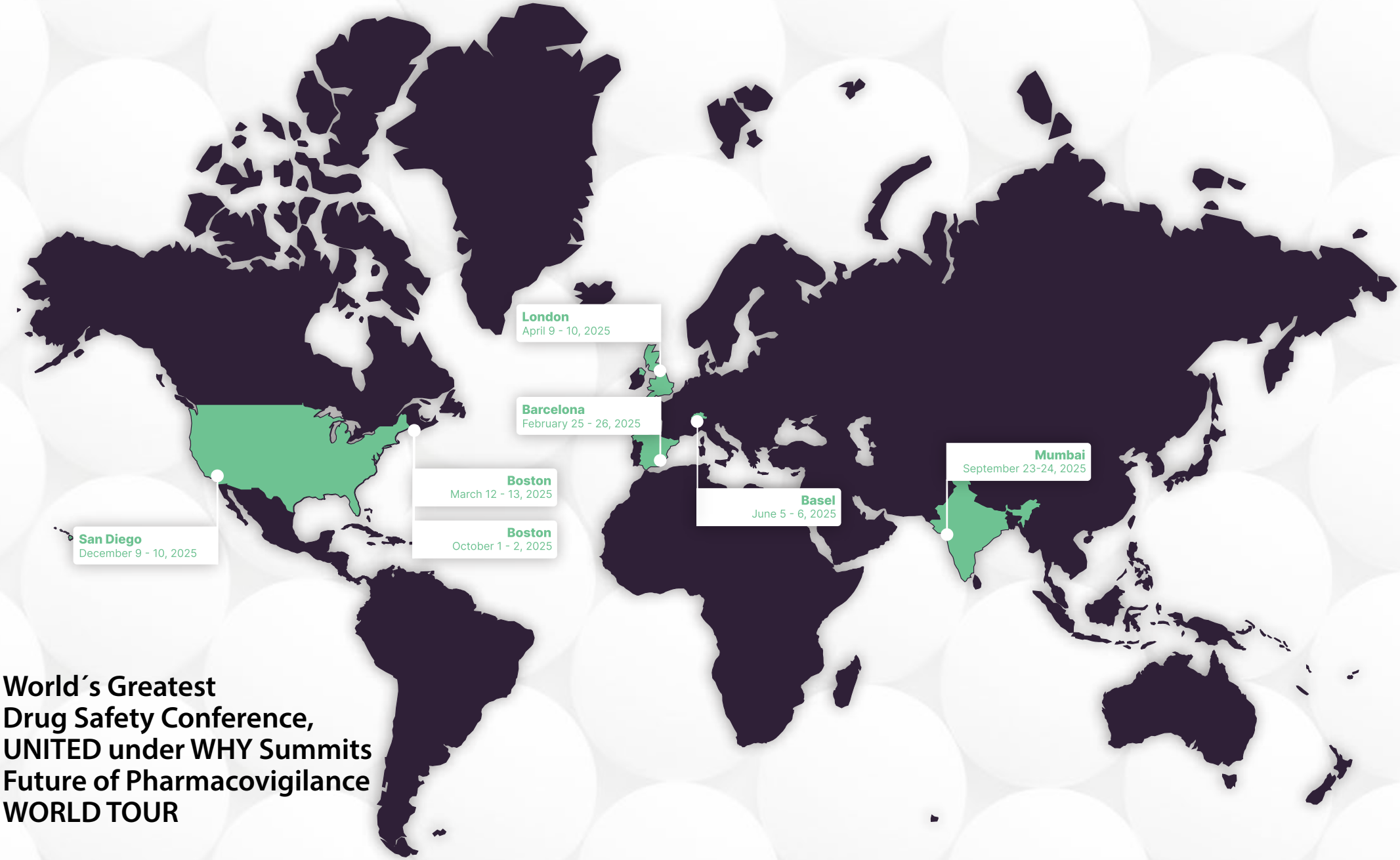
Authorities joining the summit: swissmedic

2025 Pharmacovigilance Summits Worldwide



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

Future of Pharmacovigilance

Our most prestigious European event, concluding 2024 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 2024 edition:

In the Chair

Erika Barbarosie
Associate Director - Compliance

Shaloo Pandhi
Global Head Patient safety
Sandoz

Sanjeev Srivastav
Signal Management Lead
BionTech

Michael von Forstner
Head of Safety Science
SOBI

Sibel Guerler
Head Strategy & Safety Evolution
BMS

Julien Castera
Senior Director, Global Risk Management & Safety Surveillance
Incyte

Petros Mavrogenis
Head Vigilance Process Excellence
Novartis

Luvanka Hanxhari
Global RMP Lead & Deputy of Head RMP Office
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

Dimitrios Zampatis
Global Program Safety Lead
Sandoz

Lisa Stagi
Patient Safety Country Cluser Lead
Roche

Minhaj Obeidullah
Head of Compliance & Risk Management
Novartis

Antje Baumgarten
Senior Global System Auditor
Bayer HealthCare

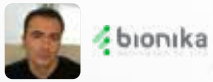
Gurpreet Singh
Vice president Integrated Safety
IQVIA

Marija Simic Koumoutsaris
Director Medical Safety
Sandoz

Jost Leemhuis
Safety Science partner & Global Business Lead
Roche

Elena Radu
Senior Global Drug Safety Physician
Basilea Pharmaceuticals

Juergen Dietrich
Senior Data Lead Scientist
Bayer



Marjan Dzeparoski
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

Agenda

Day1

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 **POST TRIAL ACCESS (PTA) PROGRAMS AND PATIENT SAFETY**
- Current regulations on PTA
- Implementation challenges
- Safety standards
- Signal, risk and benefit-risk assessment with PTA.

Dimitrios Zampatis, *Global Program Safety Lead,* **Sandoz**

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**

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

12:20 **PV REGULATORY INTELLIGENCE - BEYOND AGGREGATE REPORTS AND ICSR REPORTING**
- PV RI – setting the stage
- Current state
- Challenges
- Oversight
- Future pace
- Case study

Elena-Carmen Radu, *Senior Global Drug Safety Physician,* **Basilea Pharmaceuticals**

12:50 LUNCH BREAK

13:50 **PANEL DISCUSSION:** MODERNIZING DRUG SAFETY: PRACTICAL APPLICATIONS OF DIGITAL TRANSFORMATION IN PV
- Navigating Regulatory Acceptance and Audit Readiness in a Digital Environment
- Evaluating the Maturity of Digital Adoption in PV Functions

14:30 **LOW-END DIGITAL DISRUPTIONS IN PV:** IMPROVING LIVES WHILE CUTTING COSTS
- So-called low-end digital disruption sumps 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, *Global RMP Lead & Deputy of Head RMP Office,* **Novartis**

15:00 DIGITAL SOLUTIONS IN PV
Adriano Galati, *Digital Safety Director Pharmacovigilance & Scientific Development,* **Roche**

15:30 COFFEE BREAK & NETWORKING

16:00 **INTERACTIVE DATA SPACE TO INFORM HYPERTENSIVE PATIENTS AT RISK.**
- A German collaborative data space

Jost Leemhuis, *Safety Science partner & Global Business Lead,* **Roche**

16:30 **ROUND-TABLE DISCUSSION:** WRAP UP 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 **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**

10:10 **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**

10:40 COFFEE BREAK & NETWORKING

11:10 **COMPLIANCE AND RISK MANAGEMENT**
Minhaj Obeidullah, *Head of Compliance and Risk Management,* **Novartis**

11:40 **GVP INSPECTIONS SURVIVAL KIT:** UNVEILING THE GOOD, THE BAD AND THE DATA-FUL
Erika Barbarosie, *Associate Director Compliance*

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

12:40 LUNCH BREAK

13:40 **CASE STUDY:** SHARING EXPERIENCE IN RMP STRATEGIES DEVELOPMENT
- Presenting a detailed case study on creating risk management plans
- Highlighting the challenges and solutions in ensuring patient safety for cutting-edge treatments

Julien Castera, *Senior Director, Global Risk Management & Safety Surveillance,* **Incyte**

14:10 **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**

14:40 **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**

15:10 COFFEE & NETWORKING BREAK

15:40 **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?

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 Past Partners

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eNNOV Software for Life

PHARMORA

Quark

4C PHARMA SOLUTIONS

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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