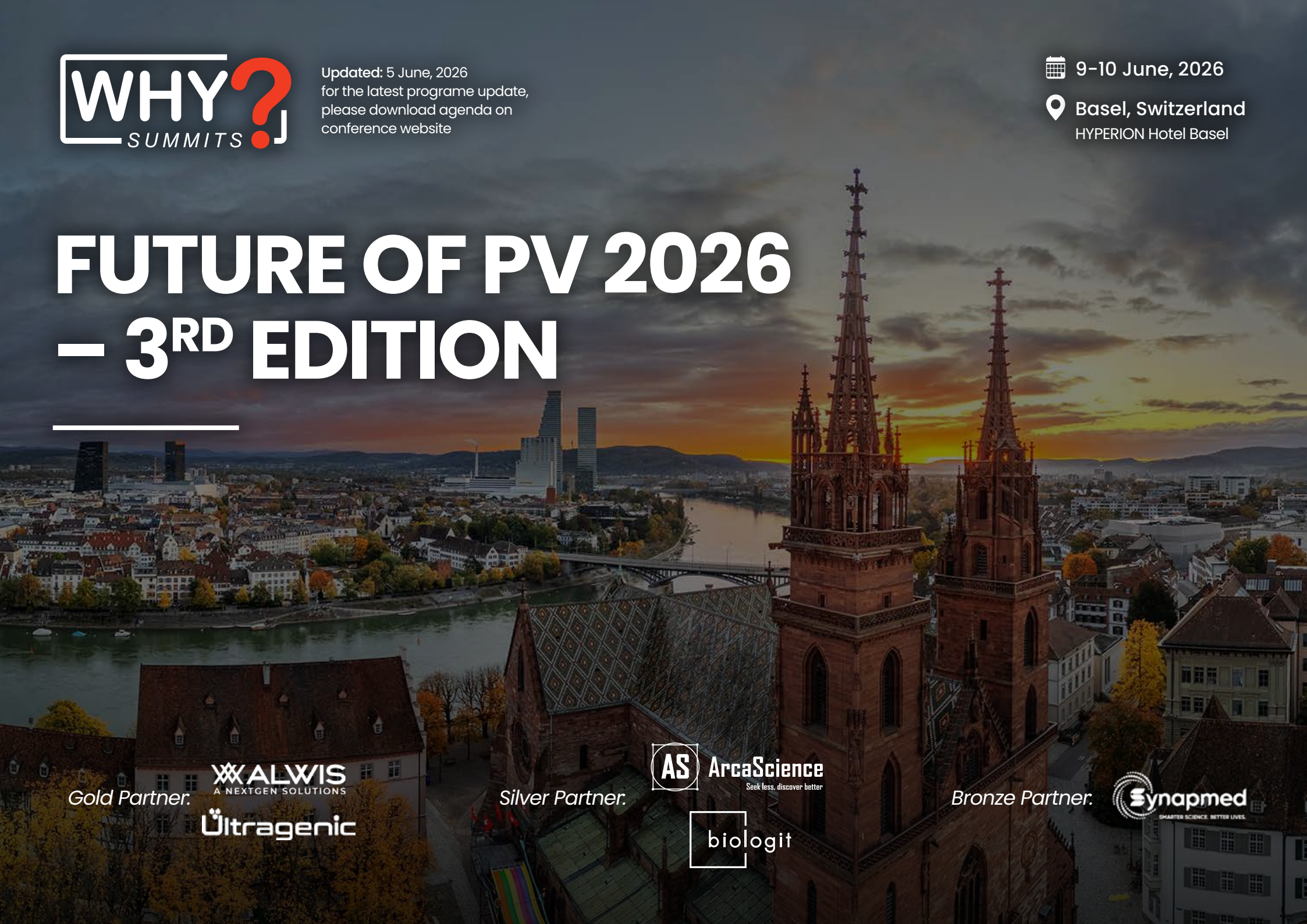
WHY? SUMMITS

Updated: 5 June, 2026
for the latest programe update,
please download agenda on
conference website

9-10 June, 2026

Basel, Switzerland
HYPERION Hotel Basel

FUTURE OF PV 2026 – 3RD EDITION



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Bronze Partner. Synapmed SMARTER SCIENCE. BETTER LIVES.

INTRODUCTION

This isn't just another drug safety conference, it's a story. A series of personal experiences from exceptional people devoted to Pharmacovigilance and protecting patients worldwide. Experts will share insights on today's evolving challenges, best practices for integrating disruptive technology into PV processes, and strategies to stay compliant with limited budgets. Topics include prioritization, methodologies for advanced therapies, AI's role in signal detection, and the future PV workforce — from Gen Z entrants to industry veterans. Discussions will also cover innovation, outsourcing, regulation, RWE data use, and public engagement. Visionary keynotes, case studies, and panel discussions will explore these themes from diverse expert perspectives. The event offers structured and informal networking to foster meaningful collaborations, all united by one mission: bringing safer medicines to patients, faster and more sustainably.

OUR MOST PRESTIGIOUS EUROPEAN EVENT, HERE'S WHAT YOU CAN EXPECT:

CONNECT & COLLABORATE: Engage with global PV, AI, RWE, and regulatory experts shaping patient safety.

INSIGHTS FROM THE TOP: Gain perspectives from visionary leaders, regulators, and innovators driving the future of PV.

HANDS-ON LEARNING: Participate in interactive workshops, roundtables, and case studies with practical applications.

AI & DIGITAL FRONTIERS: Discover AI-driven signal detection, predictive analytics, and scalable digital PV frameworks.

FUTURE-READY THINKING: Prepare for the PV workforce of 2026–2030, personalized therapeutics, and evolving regulatory landscapes.

KEY TAKEAWAYS:

- Harness AI & real-world data for smarter PV decisions
- Shift from compliance to intelligence-driven safety operations
- Apply predictive analytics for risk and case prioritization
- Build high-performing, digitally enabled PV teams
- Prepare the workforce for AI-driven PV and upskilling
- Enhance patient engagement through digital channels
- Integrate advanced therapies & personalized vaccines safely
- Optimize PV processes with automation and digital tools
- Align global regulatory expectations with innovation

YOU WILL SPEND YOUR TIME WITH:

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

TESTIMONIALS

Karen Forsha Ph.D.
L&D Change Management and Training Leader
Terumo Medical Corp.
★★★★★

„I had the opportunity to offer participants insight on how to positively impact others' well-being and influence organizational outcomes by viewing resilience, grit, and growth mindset as their leadership superpower! The dialogue afterwards was inspiring."

Surinder Dhillon
Head of Commercial PMO, International
Hologic
★★★★★

„I found the sessions were well organized, with an interesting mix of attendees from across the industry. Various key topics were covered, all pertinent to the current MedTech landscape with good discussions on common challenges and sharing of useful lessons, practical applications and future proofing strategies."

Gunther Lenz
Vice President Software R&D
Biosciences BD
★★★★★

„Digital Transformation in PPM at the #MedTechSummit! It's always inspiring to connect with fellow professionals who are equally passionate about harnessing digital tools to revolutionize project and portfolio management in healthcare. Let's continue this conversation and keep the ideas flowing!"

Renea Olsen
Post-Market Surveillance Manager, Scientific Affairs
3shape
★★★★★

„The fact that the conference is relatively small generates a very open dialog and it makes it easy to network"

Susanna Girard, MBA, PMP, ACP
Senior R&D Program Manager
J&J MedTech
★★★★★

„Great discussions! It was my pleasure to be a part of it and get to know so many great people working in the industry."

Arite Wildau
Director Patient Safety
BIOTRONIK
★★★★★

„Great open dialogue in an expert community. Many valuable presentations, panel discussions and time for networking to share best practices and different views on similar challenges. Warm atmosphere to grow as team over two fabulous days. Also excellently organized and moderated by the WHY SUMMIT TEAM. Happy to join next year as well!"

Sarah Paro
Global QMS Associate
Director
★★★★★

„Last week I had the opportunity to share my experiences and learn from industry experts at Why Summits MedTech Summit. It was an incredible experience!"

Benjamin Rochette
Vice President, Global Regulatory Affairs
Coloplast
★★★★★

„I joined the conference in Spring 2023 and really enjoyed it. The program covered several topics of direct relevance to my daily activities, while also giving me perspectives on 'macro trends' of the medical devices industry. Speakers were experts and participants motivated to interact between sessions."

INDUSTRY PIONEERS ATTENDING FROM

WHY? SUMMITS

CURRENT SPEAKERS

Mircea Ciuca
Global Head Patient Safety (interim)

Ludovic Apoux
Director Signal and Risk Management
Haleon

In the Chair

Remco Diab
Head PV, Scientific & Medical Affairs

Dimitris Zampatis
Global Program Safety Lead
Novartis

Malin Kreitz
Director of European Operations
Ultragenic

Pravin Nath
Founder & CEO
Ultragenic

Nicole Baker
CEO
Biologit

Marija Simic
Group Head Medical Safety, Global Patient Safety
Sandoz

Elena Carmen Radu
Senior Global Drug Safety Physician
Basilea

Matthias Glatz
Director, Product Management Regulatory and Pharmacovigilance
Moderna

Uwe Gudat
SVP and Chief Medical Officer
Biocon Biologics

Ashish Dwivedi
Chief Customer Officer
Synapmed

CURRENT SPEAKERS

Tea Babić
Director, Head of PV Audits and Inspections, Deputy Head PV Compliance
Teva Pharmaceuticals

Victor Adafinoaiei
Head of Digital Ethics & Compliance
Takeda

Romain Clement
Co-founder & CEO
ArcaScience

Abdul Rahim
Founder & Director
Alwis Solutions

Elena Colombo
Deputy QPPV
Jazz Pharmaceuticals

Andrea De Iacovo
Head of Pharmacovigilance
Pierre Fabre

Jost Leemhuis
Safety Science Partner and Global Business Lead
Roche

Giovanni Furlan
Head Medical Safety Operations
Sandoz

Luvanka Kalliopi Hanxhari
Senior Manager AR&RM – RMP
Novartis

Petros Mavrogenis
Global Head Vigilance Process Excellence
Novartis

Ilaria Grisoni
Exec. Dir., Head of International QPPV Office, EEA QPPV
Jazz Pharmaceuticals

NIGHT BEFORE THE EVENT

18:00 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.

CONFERENCE AGENDA

DAY 1

MORNING REGISTRATION

8:30 REGISTRATION & WELCOME COFFEE

9:00 CHAIRPERSON OPENING REMARKS

9:10 START WITH A WHY? ROUNDTABLE DISCUSSION

Meet Your Peers, Share Your Priorities, and Set Your Objectives

A short, structured icebreaker designed to help delegates connect early, promote networking, share challenges and priorities, and start the conference with more relevant conversations.

9:30

KEYNOTE: Validation of AI in Pharmacovigilance

- How to validate AI systems in pharmacovigilance in line with evolving regulatory and GVP expectations
- Building trust through transparency, explainability, and audit-ready AI frameworks
- Ensuring compliance while enabling scalable adoption of AI across PV processes and systems
- Practical considerations for integrating AI validation into global safety and regulatory operations

Giovanni Furlan, *Head Medical Safety Operations,* **Sandoz**

10:00

Presentation: Next generation of Pharmacovigilance

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

10:30

Leadership Conversation: From Signal to Strategy – Embedding Clinical Judgment in AI-Driven Pharmacovigilance

- A candid conversation on how human clinical judgment can work alongside AI to turn safety signals into real, actionable decisions in pharmacovigilance.
- Focuses on striking the right balance between automation and expert insight to improve risk assessment and patient safety.
- Shares practical challenges, regulatory perspectives, and what the future looks like for AI-powered drug safety.

Uwe Gudat, *SVP and Chief Medical Officer,* **Biocon Biologics**
Dimitris Zampatis, *Global Program Safety Lead,* **Novartis**

11:00 MORNING BREAK: COFFEE & NETWORKING

11:30

KEYNOTE: Inspection Readiness in the Age of AI – From Audit to Continuous Compliance

- Moving from periodic audits to continuous, AI-enabled compliance monitoring
- Embedding real-time data quality checks and automation to stay inspection-ready at all times
- Ensuring transparency, traceability, and explainability in AI-driven PV processes
- Building a scalable, always-on compliance culture across global safety operations

Tea Babic, *Director, Head of PV Audits and Inspections, Deputy Head PV Compliance,* **Teva Pharmaceuticals**

12:00

Reserved Presentation: Future of AI in benefit-risk assessment

Romain Clement, *Co-founder & CEO,* **ArcaScience**

CONFERENCE AGENDA

DAY 1

12:30

PANEL DISCUSSION: Regulatory AI Governance – Validation and Oversight Frameworks

- Reimagining regulatory intelligence for modern PV operations
- Navigating EMA/FDA guidelines for AI transparency, algorithmic audits, and compliant innovation pipelines.
- Practical case learnings and future outlooks

Victor Adafinoaiei, *Head of Digital Ethics & Compliance,* **Takeda**
Elena Carmen Radu, *Senior Global Drug Safety Physician,* **Basilea**
Pravin Nath, *Founder & CEO,* **Ultragenic**
Ludovic Apoux, *Director Signal and Risk Management,* **Haleon**

13:00 LUNCH BREAK

14:00

PANEL DISCUSSION: Building High-Performance Safety Teams in a Digital-First PV World

- Breaking down silos between PV, medical, regulatory, quality, and IT
- Managing cultural change alongside AI and automation adoption
- Redefining roles, responsibilities, and leadership in digital PV teams
- Enabling collaboration across global and outsourced models

Remco Diab, *Head PV,* **Scientific & Medical Affairs**
Marija Simic, *Group Head Medical Safety, Global Patient Safety,* **Sandoz**
Matthias Glatz, *Director, Product Management Regulatory and Pharmacovigilance,* **Moderna**
Petros Mavrogenis, *Global Head Vigilance Process Excellence,* **Novartis**

14:30

Reserved Presentation: The Future of Local and Global Literature Monitoring

Nicole Baker, *CEO,* **Biologit**

15:00

KEYNOTE: The European Health Data Space, PV-regulations and opportunities

- Understanding how the European Health Data Space (EHDS) will transform access to real-world data for pharmacovigilance and regulatory decision-making
- Navigating evolving PV regulations and aligning compliance with innovation, AI, and digital ecosystems
- Identifying strategic opportunities to leverage data integration for proactive safety monitoring and improved patient outcomes

Jost Leemhuis, *Safety Science Partner and Global Business Lead,* **Roche**

15:30 COFFEE BREAK & NETWORKING

16:00 ROUNDTABLES

Roundtable 1: GxP Compliance AI use for automated and enhanced Decision-Making in Patient Safety

- AI validation & auditability under GxP for patient safety decisions
- Balance between automation and human oversight in PV decision-making
- Standardizing compliant AI systems across global regulatory frameworks

Matthias Glatz, *Director, Product Management Regulatory and Pharmacovigilance,* **Moderna**

Roundtable 2: Patient-Centric PV – Engaging Patients Through Digital Interactions

- Innovation in patient reporting channels
- Improving engagement and patient safety practices

Ilaria Grisoni, *Exec. Dir., Head of International QPPV Office, EEA QPPV,* **Jazz Pharmaceuticals**
Marija Simic, *Group Head Medical Safety, Global Patient Safety,* **Sandoz**

Roundtable 3: Real-World Data: Driving Safety Evidence Beyond ICSRs

This session explores how Real-World Data (RWD) transforms modern pharmacovigilance. We discuss moving beyond spontaneous reporting to proactive safety evidence generation.

- Proactive signal detection and advanced signal assessment workflows.
- Enhanced risk characterization techniques and quantifying additional risk minimisation measure effectiveness.
- Safety evidence generation lead: a new role in the pharmacovigilance department.

Mircea Ciuca, *Global Head Patient Safety (interim)*

17:00 CLOSING REMARKS

17:10 END OF DAY 1

CONFERENCE AGENDA

DAY 2

8:30 MORNING REGISTRATION & NETWORKING COFFEE

9:00 OPENING REMARKS

9:10

Open Roundtable Discussion: Pharmacovigilance in Transition

An interactive discussion focused on the evolving pharmacovigilance landscape. Delegates will share perspectives on current priorities, emerging challenges, regulatory developments, and opportunities to strengthen patient safety through innovation, collaboration, and data-driven decision-making.

9:30

KEYNOTE: Legal Evolution – PSSF vs PSMF in a Modern PV Environment

- Understanding updated structural differences
- Local customization and global alignment
- Practical examples from regional implementation

Ilaria Grisoni, *Exec. Dir., Head of International QPPV Office, EEA QPPV,* **Jazz Pharmaceuticals**
Elena Colombo, *Deputy QPPV,* **Jazz Pharmaceuticals**

10:00

Presentation: The Future of Pharmacovigilance Starts at Intake

Understanding how strategic intake processes enable high-quality data capture, support compliance, and create the foundation for AI-driven pharmacovigilance

- Importance of Intake as the Foundation of Pharmacovigilance
- Managing Growing Safety Data Across Multi-Vigilance Ecosystems
- Digital-First Intake: Structured Data & Intelligent Workflows
- Enabling AI, Compliance, and Scalable Future-Ready Vigilance Operations

Malin Kreitz, *Director of European Operations,* **Ultragenic**

10:30 COFFEE BREAK & NETWORKING

11:00

KEYNOTE: Signal Ecosystems – Beyond Detection to Prevention

- Enhancing detection through AI, wearables, and analytics
- Moving from reactive to predictive strategies
- Advancing toward global methodological harmonization

Uwe Gudat, *SVP and Chief Medical Officer,* **Biocon Biologics**

11:30

Presentation: Where Deep PV Science Meets Real AI Engineering: A New Standard for Signal Intelligence

- *Live demo on real regulatory data*
- What "AI-native pharmacovigilance" should actually mean.
- A concrete model for how PV, Quality, and IT functions can co-own a signal intelligence operation that's regulator-grade by construction

Ashish Dwivedi, *Chief Customer Officer,* **Synapmed**

12:00

PANEL DISCUSSION: PV Risk Management – Aligning Processes, Data & Global Expectations

- Strengthening coordination between PV and medical functions
- Elevating data quality for stronger risk strategies
- Meeting evolving global regulatory expectations

Tea Babic, *Director, Head of PV Audits and Inspections, Deputy Head PV Compliance,* **Teva Pharmaceuticals**
Elena Carmen Radu, *Senior Global Drug Safety Physician,* **Basilea**
Mircea Ciuca, *Global Head Patient Safety (interim)*
Ludovic Apoux, *Director Signal and Risk Management,* **Haleon**

12:30 LUNCH BREAK

13:30

KEYNOTE: The Future of Patient Safety – Visionary Leadership in Pharmacovigilance

- Visionary leadership in pharmacovigilance driving the shift from reactive safety monitoring to proactive, prevention-focused patient safety strategies
- Leveraging AI, real-world data, and advanced analytics to enhance signal detection, risk prediction, and decision-making in PV
- Building future-ready PV organizations through digital transformation, cultural change, and preparation for personalized and complex therapies

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

14:00

Keynote: Signal Management in the AI ERA

- How artificial intelligence is reshaping signal management in pharmacovigilance, highlighting emerging capabilities
- Real-world applications, regulatory expectations, and current limitations,

CONFERENCE AGENDA

DAY 2

- Emphasizing the continued importance of expert scientific and medical judgment in an AI-enabled environment.

Dimitris Zampatis, *Global Program Safety Lead,* **Novartis**

14:30 ROUNDTABLE DISCUSSIONS

Roundtable 1: AI-Enabled PV Futures – Opportunities and Challenges

- Exploring the role of AI in next-generation PV strategies
- Aligning AI innovation with regulatory compliance and global expectations
- Lessons from personalized therapeutics, predictive safety, and digital data ecosystems

Jost Leemhuis, *Safety Science Partner and Global Business Lead,* **Roche**

Roundtable 2: The PV Workforce of 2026–2030

- Critical skills for an AI-driven PV future
- Upskilling, readiness, and capability building

Luvanka Kalliopi Hanxhari, *Senior Manager AR&RM – RMP,* **Novartis**

Roundtable 3: Global Regulatory Futures – Where Are We Headed?

- Harmonization challenges across regions
- Expectations for AI governance and oversight

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

15:30 CLOSING REMARKS BY CHAIRPERSON

16:00 COFFEE BREAK & NETWORKING

16:30 CONFERENCE CLOSURE

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WHY? SUMMITS

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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

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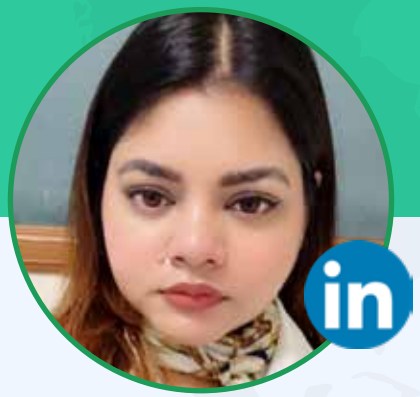
Speaking:



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Disclamer:
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REGISTRATION

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