WHY? SUMMITS

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please download agenda on
conference website

February 25 - 26

2025

EUROPEAN DRUG SAFETY & PV OUTSOURCING SUMMIT BARCELONA

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2025 Pharmacovigilance Summits Worldwide

Future of Pharmacovigilance

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

- **Meet** Europe's top Drug Safety professionals from our 2024 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

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**

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

- **Pan-European PV updates: 2025 outlook, trends and upcoming challenges**
- **Expanding pipeline & increased demand for PV outsourcing**
- **Evolving EU regulations & required strategies to adapt**
- **Aligning outsourcing strategy with the overall safety function strategy**
- **Leveraging technology to meet evolving regulatory demands**
- **Ensuring data integrity and accuracy in safety reporting**
- **Advancements in Benefit-Risk assessment and aRMMs**
- **Optimizing PV outsourcing for post-market safety data**
- **Inspection Readiness Through Effective Third Party Management & Oversight**
- **Patient-centric approaches in signal detection**
- **Data-driven PV strategies**
- **Key considerations for aligning external PV services with internal workflows**
- **Key considerations for aligning external PV services with internal workflows**

Testimonials

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

Erika Barbarosie
Associate Director PV Compliance
Gilead Sciences
★★★★★
"A huge shout out to Why Summits for the terrific organization, bringing all these talented people together. Great minds, great conversations, great topics. Buckling up for the next 😄."

Sameer Thapar
Assistant Professor & Advisor, Drug Safety and Pharmacovigilance
Rutgers University
★★★★★
"Great dialogue on key issues. Everyone shared truthful insight and did not hold back, even on negative experiences."

Daniel Naranjo
Global Safety Lead, Global Patient Safety Evaluation
Takeda
★★★★★
"Loved it. It was very practical and provided valuable insight into practical methods that are actionable for patient safety."

Lewis Atkinson
Director of Business Development for PV Drug Safety Technology
IQVIA
★★★★★
"I have thoroughly enjoyed the past 2 days of networking with my colleagues and industry professionals. Thank you to Why Summits for wonderful organisation! I look forward to Basel later in the year!"

Souhail Debaghi
Director of Sales
TriNetX
★★★★★
"Really enjoyed the Pharmacovigilance & RWE Forum by Why Summits! What I loved most, is how friendly, collaborative and intimate the PV community really is. This is of course great to see, as a vendor, but more so a potential patient receiving the outputs of this heroic work!"

Kyle Derstine
Principal Product Leader, Digital Transformation
Genentech Product Development
★★★★★
"I just think what's also wonderful is that it's very local organized conferences but people fly in from everywhere and so you do get a really good representation across like 40 different companies – big, small, medium size and that's trully where the value of this collective is."

Cláudia Meneses
Senior Pharmacovigilance Officer
Sanofi
★★★★★
"Thanks to the 9th Global Pharmacovigilance & RWE Forum speakers, 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."

Vijay Singh
Associate Director, Product PV Device Digital Safety
UCB
★★★★★
"Thank you Why Summits for the opportunity to share my thoughts on Advancements & Challenges in Signal Detection. It was great to share my thoughts along with other panelists."

Our Partners

Biologit"Accelerating Patient Safety: Leading with Evidence, AI and Scientific Expertise.

Biologit MLM-AI is a state-of-the-art platform for monitoring scientific literature to identify adverse events and emerging risks throughout a product's lifecycle, from clinical development to post-marketing. Designed for teams of all sizes, it combines a flexible workflow with a unified global and local scientific database, enhanced by unique AI-driven screening and productivity tools. These features enable fast, accurate, and fully traceable results for all safety surveillance needs.

Biologit Database is a robust, continuously updated repository of scientific literature, optimised for compliant regulatory searches. It integrates global and regional sources into an intuitive interface, delivering high-quality results for monitoring adverse events and potential risks. With over 65 million entries and 40,000 new articles added daily from 120,000 journals across 170+ countries, it ensures comprehensive coverage aligned with FDA, EMA GVP and global standards."

Quark knows content. The company revolutionized desktop publishing and provides content automation, intelligence and design software for end-to-end content lifecycle management. Quark helps to modernize content ecosystems so they can create complex print and digital layouts, automate omnichannel publishing of mission-critical documents, and analyze production and engagement insights for the greatest return on their content investments.

Industry Pioneers Attending From

Meet the first onboarded speakers to 2025 edition:

Galyna Cordero
QPPV, Head of pharmacovigilance
JSC Farmak

Sanket Mahajan
Safety Scientist, Pharmacovigilance Shionogi Europe
Shionogi Europe

Stefanie Amend-Mall
Director Patient Safety HUB Europe
Sandoz

Darko Krnic
Head of Pharmacovigilance
Pharma&

Ivanna Mikhailovna Rosendal
Senior Director, Global Head of Digitalization
Ascendis Pharma

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

Offiong Ani
Associate Director, Third Party Strategy & Oversight, Worldwide Patient Safety
Bristol Myers Squibb

Annette Humes
Global Head of Safety Resource & Alliance Management and Chief of Staff (Safety)
F Hoffmann La Roche

In the Chair

Gurpreet Singh
Vice President, Managing Director Integrated Safety
IQVIA

Santiago Schiaffino
Senior Director, Patient Safety Biopharma - Global Patient Safety Biopharma Organization | R&D CMO
AstraZeneca

Gaetano Aiello
Sr Manager, EU/International PV & QPPV Office and PSMF Admin
Jazz Pharmaceuticals

Nicole Baker
CEO
BioLogit

Emerson Welch
VP Global Marketing
Quark

Carlos de Pablos Martínez
QPPV Office Specialist
Argenx

Dr. Joan D'souza
Pharmacovigilance and Quality Consultant (DACH region)

Conference Agenda

DAY 1

DAY 0 – NIGHT BEFORE THE EVENT

18:30 MEET & GREET

Welcome to our event! We are so honored and grateful to have you with us! Come and join us for some drinks, where you will be able to do an early bird registration along with some firsthand networking! All the delegates will start arriving and we will all have a chance to get to know one another - the sooner the better. Drinks, conversations, handshakes, smiles, hugs, whether with your old or new friends from the industry - everyone is welcome!

8:30AM Morning Registration and early birds networking coffee

SUMMIT OPENING: PHARMACOVIGILANCE LANDSCAPE – 2025 TRENDS & CHALLENGES

9:00AM

OFFICIAL START OF EUROPEAN DRUG SAFETY & PV OUTSOURCING SUMMIT WITH OPENING REMARKS OF THE CHAIRPERSON

9:10AM

GET TO KNOW THE ROOM – SPEED NETWORKING SESSION

9:20AM

KEYNOTE: STRUCTURED BENEFIT-RISK ASSESSMENT IN ASTRAZENECA

- Benefit-risk assessment is inherently a multifaceted, cross-functional artifact
- The successful implementation of an sBR procedural framework is the collective commitment of all stakeholders involved
- Safety strategies for investigational products being administered by our Global Patient Safety as an ongoing process that spans various functions, including clinical development, patient safety, biostatistics, regulatory, and epidemiology functions

Santiago Schiaffino, *Senior Director, Patient Safety Biopharma - Global Patient Safety Biopharma Organization | R&D CMO,* **AstraZeneca**

9:50AM

AUTOMATION OF A PROBABILISTIC TOOL FOR CAUSALITY ASSESSMENT

- Description of the new probabilistic method of causality assessment
- Automation of the tool by means of Large Language Model and predefined data-sheets
- Comparison of automated (AI driven) vs manual (human) assessment
- Future use of the tool to carry out an automated semiquantitative signals detection

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

10:20AM

ROUND-TABLE DISCUSSIONS: NAVIGATING THE FUTURE OF PHARMACOVIGILANCE - KEY TRENDS, INNOVATIONS, AND CHALLENGES AHEAD

- Emerging technologies to keep an eye on.
- The Growing Complexity of Risk Management Plans (RMPs) and Benefit-Risk Assessments
- Share success stories of patient engagement initiatives that have improved pharmacovigilance outcomes.
- Next-generation signal detection - Collaborative strategies for cross-industry signal intelligence sharing
- The Expanding Role of Pharmacovigilance in Pre-Market Drug Development

10:50AM MORNING BREAK: COFFEE, CAKE & NETWORKING

11:20AM

HOW TO DEVELOP A STRATEGIC CATEGORY PLAN FOR PV OUTSOURCING

- A robust vendor plan for PV activities is essential for delivering value for the business.
- Ensuring security of supply, innovation and agility with changing business needs.
- In an ideal world, a vendor plan could be developed from scratch, but in most cases, an active base of PV vendors will be inherited by the person taking on the outsourcing role.
- Understanding the PV category and identifying where procurement could be of help.
- How a framework for PV outsourcing was developed and how the criteria for strategic vendors were defined.

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

Conference Agenda

DAY 1

11:50AM

PSMF CHALLENGES AND OPPORTUNITIES

- Strategy to maintain the EEA PSMF and the other Local PSMFs to guarantee the QPPV Oversight

Gaetano Aiello, *Sr Manager, EU/International PV & QPPV Office and PSMF Admin,* **Jazz Pharmaceuticals**

12:20AM

ROUND-TABLE: ALIGNING PV OUTSOURCING WITH STRATEGIC BUSINESS GOALS

- Common pitfalls in PV outsourcing and how to mitigate them.
- The future of PV outsourcing: trends & innovations.
- What are the key challenges PV leaders face in outsourcing today?
- Aligning your PV outsourcing strategy with overall safety function strategy.

13:00PM LUNCH BREAK

14:00PM

POST-LUNCH OPEN-DISCUSSION

14:20PM

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**

14:50PM

KEY CONSIDERATIONS FOR INHOUSE VS OUTSOURCING PV

- Best practices for creating robust organizational structures that support quality management
- Finding the right balance: in-house vs. Outsourced
- Key factors influencing the decisions

Darko Krnic, *Head of Pharmacovigilance,* **Pharma&**

15:20PM Coffee & Cake Break

15:50PM

PANEL DISCUSSION: DIGITAL TRANSFORMATION AI & INNOVATION IN PHARMACOVIGILANCE

- The increasing volume and complexity of safety data demands new digital solutions.
- How AI is Transforming PV.
- Regulatory Considerations and AI Adoption.
- AI & Machine Learning in Signal Detection and Case Processing.

16:50PM END OF DAY 1

Conference Agenda

DAY 2

8:30AM Morning Registration and early birds networking coffee

9:00AM

OPENING SPEECH & INTRODUCTION

9:10AM

CHALLENGES AND OPPORTUNITIES WHEN INTEGRATING INTERNAL AND EXTERNAL MEMBERS TO GLOBAL PV NETWORK

- Points to consider when partially outsourcing local PV contact person
- Ensuring compliance with internal procedures and agreements with business partners

Carlos de Pablos Martínez, *Emerging & Partner Markets Regional PV Manager,* **Argenx**

9:40AM

KEY ASPECTS OF SAFETY MONITORING, FOCUSING ON SIGNAL DETECTION METHODOLOGIES, RISK MITIGATION FRAMEWORKS, AND REGIONAL REGULATORY EXPECTATIONS

- Ensuring patient safety is the cornerstone of clinical trials, particularly in the DACH region within stringent regulatory frameworks and evolving safety standards
- Effective signal evaluation and proactive risk management strategies are essential to maintaining compliance and safeguarding trial participant

Dr. Joan D'souza, *Pharmacovigilance and Quality Consultant (DACH region)*

10:10AM

BUILDING A COMPLETELY NEW STAND-ALONE PV SYSTEM

- What were the key success factors and key challenges during the build up phase for a company present in 140 countries and portfolio of 900+ small molecules and 10 bio-similars in the market?
- Which key challenges were to overcome in the first 18 months post go live?
- The fire test: Experiences and learnings from the inspections after spinning off

Stefanie Amend-Mall, *Director Patient Safety HUB Europe,* **Sandoz**

10:40AM NETWORKING BREAK

11:10AM

CASE STUDY: THE RED THREAD - THE BENEFITS OF ALIGNING YOUR PV OUTSOURCING STRATEGY TO THE BIGGER PICTURE

- Aligning outsourcing strategy with overall safety function strategy
- Best practices for maintaining quality, accountability, and regulatory adherence
- Opening up other opportunities to add value through outsourcing

Annette Humes, *Global Head of Safety Resource & Alliance Management and Chief of Staff (Safety),* **Roche**

11:40AM

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**

12:20PM

PANEL DISCUSSION: AI'S POTENTIAL IN HELPING PRODUCE PSMFS AND OTHER HIGHLY REGULATED DRUG SAFETY DOCUMENTS

- Is it safe? Is it reliable?
- Is it realistic to think AI can do this on its own or does it need structured data, humans in the loop and more?
- What you should expect from AI when it comes to authoring and producing PSMFs, PSURs and more?

13:00PM LUNCH BREAK

14:00PM

POST-LUNCH OPEN-DISCUSSION

Conference Agenda

DAY 2

14:20PM

ROUND-TABLE DISCUSSION: THE ROLE OF PROJECT MANAGEMENT IN PHARMACOVIGILANCE: ENSURING EFFICIENCY, COMPLIANCE, AND QUALITY

- Managing Complex Pharmacovigilance Projects and multi-stakeholder collaboration (internal teams, CROs, vendors, regulators).
- PV inspection readiness: A project management approach.
- Preparing for regulatory audits with structured project plans.
- Do we have the right talent and skill sets to support next-gen PV?

15:00PM

ROUND-TABLE: QPPV KEY FOCUS AREAS TO CONSIDER – EXPERT OPINION

- How do you see QPPV changing and what should we prepare for?
- Signal evaluation and proactive risk management.
- Structured benefit-risk assessment.

15:00PM Networking coffee break

15:30PM

OPEN-DISCUSSION

- Summary of main focus points to consider
- Key take-aways and considerations

16:00PM CLOSING REMARKS

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 Partners

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