WHY? SUMMITS

Updated: 20 May, 2026
for the latest programe update, please download agenda on conference website

8 - 9 December
2026

Boston
USA

4TH AMERICAN DRUG SAFETY & RISK MANAGEMENT CONFERENCE 2026

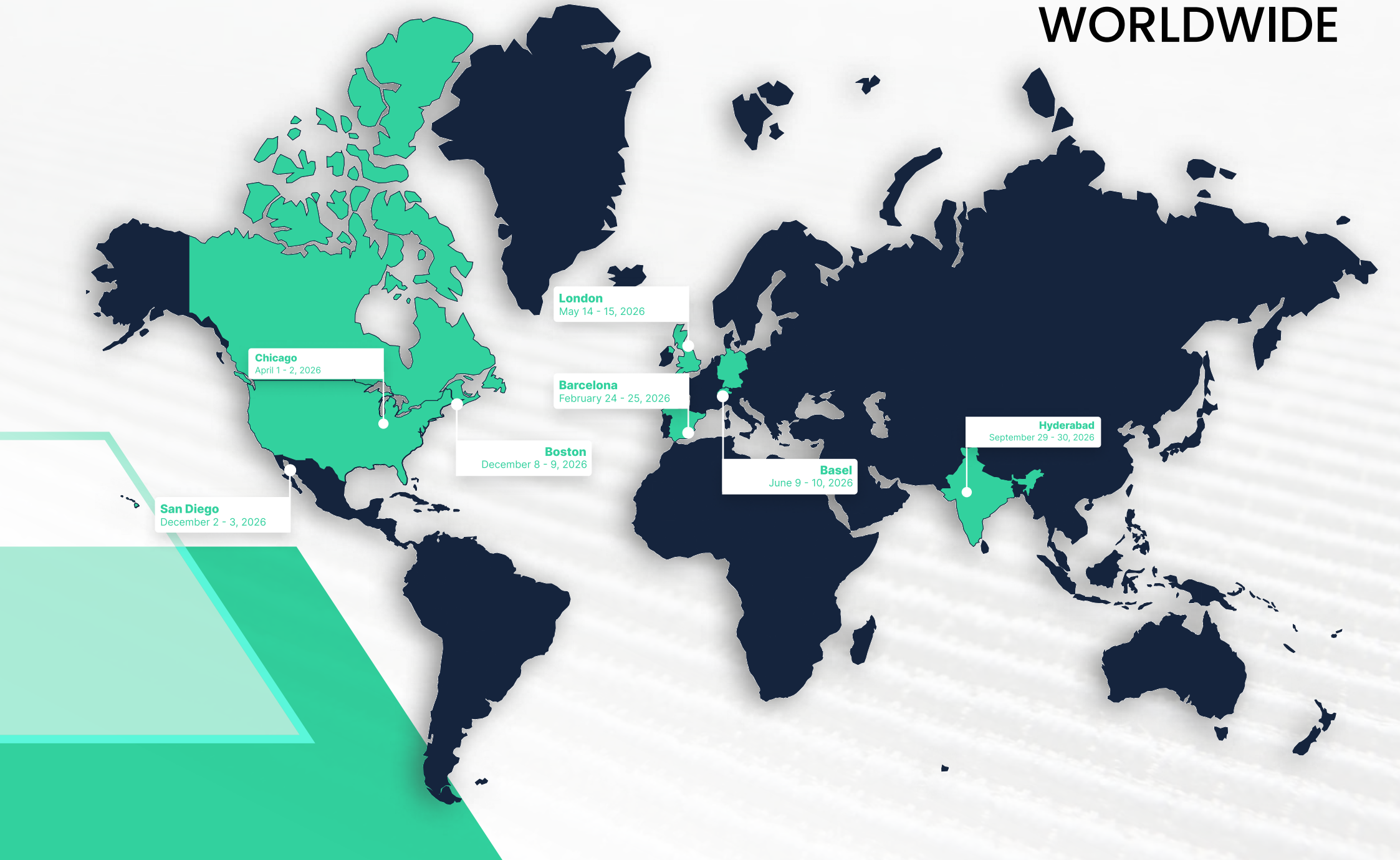
Gold Sponsor

ALWIS
A NEXTGEN SOLUTIONS

2026 PHARMACOVIGILANCE SUMMITS

WHY? SUMMITS

WORLDWIDE



FUTURE OF PHARMACOVIGILANCE

WHY? SUMMITS

Our prestigious 4th American Drug Safety & Risk Management conference, a cornerstone of our Pharmacovigilance World Tour.

- **Join** America's Leading Drug Safety Professionals
- **Gain** insights into the most pressing issues facing drug safety today.
- **Discuss** the vision for 2027 and lessons of 2026.
- **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

- **VPs, Global Heads and Senior Directors of:**
- **Drug Safety**
- **Pharmacovigilance**
- **REMS**
- **Risk Management**
- **Signal Detection**
- **Regulatory & Compliance**
- **Post-market research**
- **PV audit**
- **Digitization**
- **Automation**
- **Operations**

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 Boston Knowledge-Focused Meeting will cover the following emerging topics:

- **Strengthening Risk Mitigation Strategies**
- **Tech Innovation: Digital Solutions for Risk Management**
- **Evolving REMS Programs & Regulatory Expectations**
- **Risk-Based Decision Making in Pharmacovigilance**
- **AI: The Future of Safety Monitoring**
- **Risk Communication & Stakeholder Collaboration**
- **Post-Market Risk Management Best Practices**
- **Future of REMS & Global Risk Management Regulations**
- **The Next Decade of REMS & Risk Management**
- **The Power of Cross-Functional Collaboration in PV**
- **Enhancing PV Operations with AI & Automation**
- **AI-Driven Signal Detection & Risk Prediction**
- **The Business Case for AI in Pharmacovigilance**
- **Optimizing Safety Signal Management through Collaboration**
- **The Role of Real-World Evidence**

OUR SPEAKERS AND PANELISTS

WHY? SUMMITS

William Blumentals
Head of Pharmacoepidemiology, Specialty Care
Sanofi

Ankit Lodaya
Senior Director Pharmacovigilance
Beam Therapeutics

Slava Akmaev
Chief AI Officer, Interim Chief Operating Officer
BPGBio

Mariette Boerstoel Streefland
SVP, Worldwide Patient Safety Officer
BMS

Peter Henstock
Machine Learning Group Leader
Incyte

Subhayan Das
Director BI&T, Data & Analytics- Patient Safety & Regulatory
BMS

Priyanka Chhikara
Senior Director, Head of Pharmacovigilance Scientists
CSL

Mamatha Chandrashekar
Safety Systems Program Lead
CSL

Sudhir Shandilya
Director, Digital Delivery & Operations
Sanofi

Hilary Yiokarinis
Director of Quality
Ultragenyx

Abdul Rahim
Founder
Alwis

Ashraf Youssef
Global Senior Medical Director, Post Marketed Products, Global Safety Lead
Takeda

Ashish Dwivedi
Chief Customer Officer
Synapmed

Samy Rabb
Senior Manager REMS Operations
TEVA

Vasu Miduturu
Director, Pharmacovigilance Operations
Tango Therapeutics

Kapil Bhutada
Head of Pharmacovigilance Safety Operation and Compliance
AskBio

Michael Cheung
Executive Director, Global Risk Management Lead, REMS and Risk Management Strategy
Bristol Myers Squibb

Ash Higgins
Associate Director, Pharmacovigilance Science
Deciphera

Bikram Kabir
Senior Director - Global Safety Officer
Alkermes

TESTIMONIALS

Gigi Atalla
Vice President, Head of Global Drug Safety & Pharmacovigilance
Genmab
★★★★★
"Participating in the American Drug Safety Summit was a truly rewarding experience. The energy in the room, the depth of conversations, and the shared commitment to transforming pharmacovigilance made it an inspiring and impactful event. I walked away with new perspectives, meaningful connections, and a strong sense of momentum for what's ahead."

Kal Elhoregy, RPh., PA.
Senior Director, Global Risk Management
Amneal
★★★★★
"The conference fosters invaluable connections and drives meaningful collaboration, offering an engaging platform for dynamic interactions within Global Pharmacovigilance & Risk Management, exchange of ideas, and shared growth among participants to ensure patient safety and regulatory compliance."

Karthik Babu
Consumer Healthcare Global PV Operations Head
Sanofi
★★★★★
"I thoroughly enjoyed the interactive and spontaneous discussions on key pharmacovigilance topics, ranging from Gen AI to PV regulatory frameworks. The conference brought together a focused group of PV professionals, providing ample opportunities to connect and network with like-minded individuals. Overall, it was a successful conference and met its objectives."

Israel Bocanegra
Associate Director, Business Development
Pharmacovigilance Technology Solutions
★★★★★
"I want to express my gratitude to Lubos and the Why Summits team for a well-organized and informative Pharmacovigilance event. The comprehensive agenda, featuring a variety of expert presenters and engaging panel discussions, provided valuable insights and fostered productive networking. I'm eager to participate in future Why Summits events."

Katarina Ilic
Expert Consultant
Drug Safety, Clinical Pharmacology, Clinical Development, Pharmacoepidemiology
★★★★★
"I heard great things about the event from those who attended, and those who didn't manage to attend this year regret."

Andrew Mitchell
Chief Executive Officer
YEZA.ai
★★★★★
"WhySummit's Pharmacovigilance Conference in Boston exceeded expectations for all. As chair, I was impressed by the intimate scale and quality of interactions given how tricky it can be to strike the right balance of being large enough to bring together diverse perspectives and new connections, yet small enough to foster meaningful dialogue and substantive interactions. Both sponsors and attendees valued lively discussions that went beyond typical sessions (and without being overly 'salesy'). Lubos and his team deserve credit for curating a program that was both informative and interactive, creating an environment where PV professionals could truly connect, share and learn from each other. Looking forward to next year."

Apoorva Anil Joshi
Senior Pharmacovigilance Product Scientist
Genentech
★★★★★
"The American Drug Safety Summit 2025 was a great event to learn from industry experts about the evolution of patient safety. It was very interesting to see how AI is being leveraged in data-intensive projects to improve patient outcomes. The introduction to the REMS Industry Consortium was a highlight, and their work is truly inspiring."

Robert Huber
Co-Founder and Chief Product Officer
Veridat
★★★★★
"Fabulous meeting today, Lubos. This is a fabulous opportunity for us to shape the future, not just that we can be the conduit to current advances, but we can go beyond that with our military grade solutions."

Alison Purdon
Senior Director, MedOps, Quality & Compliance, Engagement Oversight
Genentech
★★★★★
"The event was incredibly well-organized, and we enjoyed both the thoughtful conversations and the chance to connect with others in the industry. Your efforts in bringing together leaders in drug safety to drive meaningful dialogue do not go unnoticed, and we are grateful to have been a part of it. Thank you again for your kind invitation and for making the experience such a great one. I look forward to staying in touch and continuing the conversation!"

Mina Ebeid
Director, Global Drug Safety
Genmab
★★★★★
"I thoroughly enjoyed participating in the Why Summits pharmacovigilance conference. The topics were not only timely and relevant but also deeply engaging, sparking meaningful discussions. I especially appreciated the collaborative atmosphere, which created a great opportunity to connect with colleagues across the field and exchange valuable insights."

Vasudev Sureddy
Executive Director & COO
ADVITY RESEARCH
★★★★★
"This event provided great opportunity to network with Industry peers & thought leaders and explore new ways of working. Especially in the new AI era; "on how Pharmacovigilence industry is progressing and how we need to adapt to the change". Insights from presentations and panel discussions are adorable. I left with great ideas and new connections in my network to collaborate with and grow further."

Maja Barac
Director, EU Qualified Person for PV
PharmaVigil
★★★★★
"Attending this year American Drug Safety Summit 2025 in Boston by Why Summits was an absolute discovery for me. Attendees were not numerous but they represented top-notch leaders from pharma industry in the EU and USA. Discussions were so exciting and constructive - I enjoyed every moment of it. I am truly grateful to Jan, Lubos and Zuzana for such a smart planning of this important event"

Marissa StLouis
Safety Partnering Lead
Genentech
★★★★★
"Excited to have participated in the American Drug Safety Summit in Boston, MA! ❄️. It was an honor to highlight the successful partnerships and collaborations between our Safety and Social teams over the past couple of years as well as connect and learn from with industry Subject Matter Experts. A key takeaway for me: AI is coming/ AI is now- How can we utilize this tool, not only to bring efficiencies into our work, but also focus on value-add and increasing quality of work? Thank you to Alison Purdon for your sponsorship and mentorship over the past several years and inviting me to join in on this opportunity! Thank you to Lubos K.and the #WhySummits team for all of your partnership and efforts creating a memorable event!"

CONFERENCE AGENDA

Day 0
7 Dec 2026

18:00 NIGHT BEFORE THE EVENT - 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!

Day 1
8 Dec 2026

8:30 REGISTRATION OPEN & WELCOME COFFEE

9:00

OPENING REMARKS FROM WHY SUMMITS AND THE CHAIRPERSON

9:15

OPENING ROUND-TABLE DISCUSSION: KEY INSIGHTS

- Must-knows of the current industry status
- Key focus areas, challenges and opportunities

9:45

THE NEW ERA MOVING TOWARD PROACTIVE, DATA-DRIVEN RISK IDENTIFICATION

- From reactive reporting to proactive intelligence
- Integrated benefit-risk frameworks are shifting from compliance overseer to strategic decision-maker
- What this transformation means operationally

10:15

STRENGTHENING RISK MANAGEMENT IN PHARMACOVIGILANCE PARTNERSHIPS: STRATEGIES FOR COMPLIANCE AND ACCOUNTABILITY

- Early signal identification requires structured partnerships with clear legal frameworks that define risk ownership and accountability across all parties.
- Regulatory transparency and standardized reporting pathways must be embedded into partnership agreements — not added after the fact.
- Regular audits, data protection protocols, and operational alignment are the operational backbone of any effective PV partnership.

10:45 COFFEE & NETWORKING BREAK

11:15

THE EVOLVING REGULATORY LANDSCAPE: WHAT'S CHANGED AND WHAT'S COMING

- 2025 FDA updates introduced accelerated reporting timelines for serious adverse events and mandatory use of structured data formats for FAERS submissions
- The evolution of REMS reflects a long-term shift toward balancing patient safety with regulatory efficiency

11:45

PANEL DISCUSSION: LEADING REMS PROGRAMS DURING TIMES OF TRANSITION

- Lesson learned from:
- Transitions from Single REMS to Share System REMS
- Implementing Major Modifications or Operation Changes
- Vendor Changes

12:25

ROUND-TABLE DISCUSSION: REMS INSPECTION READINESS

- Preparing for an inspection

13:15 LUNCH & NETWORKING

14:00

ROUND-TABLE DISCUSSION: 1ST STEPS IN RISK MITIGATION

- Next-generation signal detection & risk mitigation
- Global regulatory harmonization readiness

CONFERENCE AGENDA

Day 1
8 Dec 2026

14:45

LEADING REMS PROGRAMS DURING TIMES OF TRANSITION

- Lesson learned from:
- Transitions from Single REMS to Share System REMS
- Implementing Major Modifications or Operation Changes
- Vendor Changes
- REMS Releases

15:20

STRENGTHENING RISK MANAGEMENT IN PHARMACOVIGILANCE PARTNERSHIPS: STRATEGIES FOR COMPLIANCE AND ACCOUNTABILITY

- Early signal identification requires structured partnerships with clear legal frameworks that define risk ownership and accountability across all parties.
- Regulatory transparency and standardized reporting pathways must be embedded into partnership agreements — not added after the fact.
- Regular audits, data protection protocols, and operational alignment are the operational backbone of any effective PV partnership.

15:50 NETWORKING & REFRESHMENT BREAK

16:20

PRECISION PHARMACOVIGILANCE AND ITS PRAGMATIC ADOPTION

- In today's day and age, how can we better identify risks and predict adverse effects at individual patient level.
- Role of predictive biomarkers and real world data
- SImple risk stratification strategies that PV professionals can use in routine activities

16:50

CLOSING ROUND-TABLE: THE NEXT DECADE OF PV& RISK MANAGEMENT

- How can we manage the increasing complexity of product portfolios?
- Vendor & outsourcing over-reliance: what can be done to avoid gaps in risk mitigation?
- Global harmonization: FDA REMS vs EMA RMP expectations and changes
- Getting involved & staying ahead of the curve

17:20 WRAP-UP & KEY TAKEAWAYS FROM DAY 1

CONFERENCE AGENDA

Day 2
9 Dec 2026

8:30AM REGISTRATION OPEN & WELCOME COFFEE

9:00

OPENING REMARKS FROM WHY SUMMITS AND THE CHAIRPERSON

9:10

OPENING ROUND-TABLE DISCUSSION: WHY ARE WE FAILING TO IMPLEMENT NEW TECHNOLOGIES ON TIME?

- A risk adverse culture – can it change?
- The vendor landscape fragmentation
- Integration of legacy PV systems
- Lack of clear regulatory guidance

9:30

AI IN PV RISK MANAGEMENT

- THE INDUSTRY IS LARGELY AUTOMATING TASKS, NOT TRANSFORMING RISK-BASED DECISION-MAKING.
  - At what point can an AI-generated insight be considered reliable enough to inform a Risk Management Plan or regulatory strategy decision?
- EVALUATING RISK MINIMIZATION MEASURES WITH AI
  - Assessing whether risk minimisation measures are actually working is one of the most valuable things AI could do in PV. Why is it still the weakest link, and what are the practical, regulatory, and organizational barriers to getting there?
- IF "CONTINUOUS RMP" POWERED BY AI IS MOSTLY STILL A ROADMAP, WHAT ARE THE REALISTIC FIRST STEPS PV DIRECTORS CAN TAKE TODAY?
  - Most organizations operate in siloed safety systems without a continuous RMP framework. What could a realistic 12–24 month transformation look like, and what governance, data, and change management prerequisites must come first?"
- AI CAN TECHNICALLY EXTRACT SIGNALS FROM REAL-WORLD DATA, SO WHY ISN'T IT INFLUENCING OUR RMP DECISIONS YET?
  - The technology exists. The data exists. Yet for most organizations, RWD still doesn't meaningfully feed into continuous risk assessment or RMP updates. Is the barrier the data quality, regulatory, organizational? As PV Directors, which of those barriers do we actually own, and where do we start?

10:00

MANAGING THE RISK OF AI IN PV

- Opportunity & risk in equal measure
- AI's "black box" problem is PV's biggest liability
- FDA's 2026 AI guidance on a risk-based credibility model
- Regulatory bodies are focusing on four non-negotiables for AI in PV: data quality, patient privacy, system validation, and timely adverse event reporting

10:30 COFFEE & NETWORKING BREAK

11:00

PANEL DISCUSSION: AI & EMERGING TECHNOLOGIES

- What's stopping us from implementing new technologies?
- You cannot implement AI agents into old structures
- How AI will shape PV over the next decade
- Ethical and regulatory challenges in AI adoption – global market considerations
- Balancing automation with human expertise

11:40

THE ROLE OF REAL-WORLD EVIDENCE IN PHARMACOVIGILANCE

- Leveraging RWE for better risk assessment
- Integration of RWE with AI technologies
- Addressing regulatory challenges

12:10

OUR PV LANDSCAPE: WHERE WE STAND TODAY

- Current marketed products, pipeline stage, and active post-market commitments
- Ongoing REMS programs and open FDA safety queries
- Key gaps vs. evolving FDA expectations

12:40 LUNCH BREAK

13:40

RISK MONITORING SPECIFIC TO GENE THERAPIES

- Unique safety profile: long-term risks, delayed adverse events, and irreversible effects
- Importance of long-term patient follow-up and registries (often 15 years or more)

14:10

THE POWER OF CROSS-FUNCTIONAL COLLABORATION IN PV

- Breaking down silos between PV, Clinical, Regulatory & Medical Affairs
- Real-world collaboration case study
- Improving decision-making in risk management

CONFERENCE AGENDA

Day 2
9 Dec 2026

14:40

PANEL DISCUSSION: CROSS-FUNCTIONAL TEAMS & COLLABORATION IN RISK MANAGEMENT

- Aligning clinical, regulatory & safety teams for better PV outcomes
- Ensuring all perspectives are considered in evaluating risks
- How collaboration improves technology implementation
- Enabling continuous reassessment of the product's benefit-risk profile throughout its lifecycle

15:10 COFFEE & NETWORKING BREAK

15:40

INTEGRATION OF RWD IN SIGNAL MANAGEMENT

- Broaden detection with RWD beyond ICSRs
- Validate signals using real-world benchmarks
- Enable proactive risk management

15:40

INTEGRATION OF PHARMACOVIGILANCE AND MANUFACTURING IN ENSURING DRUG SAFETY & QUALITY

- Pharmacovigilance and Manufacturing alignment to strengthen regulatory compliance
- Case examples: The Heparin Case, Labelling Errors, Root Cause Investigation in Manufacturing

16:10

FAERS & PROACTIVE SIGNAL DETECTION

- FDA requirements for changes to product labeling, require development or modification of a REMS

16:40

CLOSING PANEL: SUMMARY OF CONFERENCE HIGHLIGHTS & WHAT'S NEXT FOR PV RISK MANAGEMENT, TECHNOLOGY & COLLABORATION?

- Feedback: what's important to discuss in 2026?
- Drawing the line between hype and reality in AI: what aspects should we be focusing on?
- Key management functions we'd like to hear more of
- Shaping a regulations guideline

17:10 KEY TAKEAWAYS & CLOSING REMARKS

OUR PAST PARTNERS

WHY? SUMMITS

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

CONTACT US

Updated: 20 May, 2026
for the latest programe update,
please download agenda on
conference website

WHY? SUMMITS

If you are interested in
SPEAKING

Jan Cizek
jan.cizek@whysummits.com

If you are interested in
SPONSORSING

Rakesh Multani
rakesh@whysummits.com

If you are interested in
ATTENDING

Isaac Kaitho
isaac.kaitho@whysummits.com

Disclamer:
Please note - all of the information in this document is subject to change at any time. Whilst every effort has been made to ensure the accuracy of the information, statements and decisions recorded in them, their status will remain that of a draft until such time as they are confirmed as a final version prior the subsequent meeting, Additionally, the user information is only valid at a certain moment in time and is subject to change due to movement and changes in bit rate requirements.

"Always be Curious"

www.whysummits.com

REGISTER HERE

$ 2349