



Updated: 1 October, 2025
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2nd American Drug Safety Summit



Boston | Massachusetts

Wyndham Boston Beacon Hill
5 Blossom Street, Boston,
Massachusetts 02114, United States
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16 - 17 October 2025 | 2025

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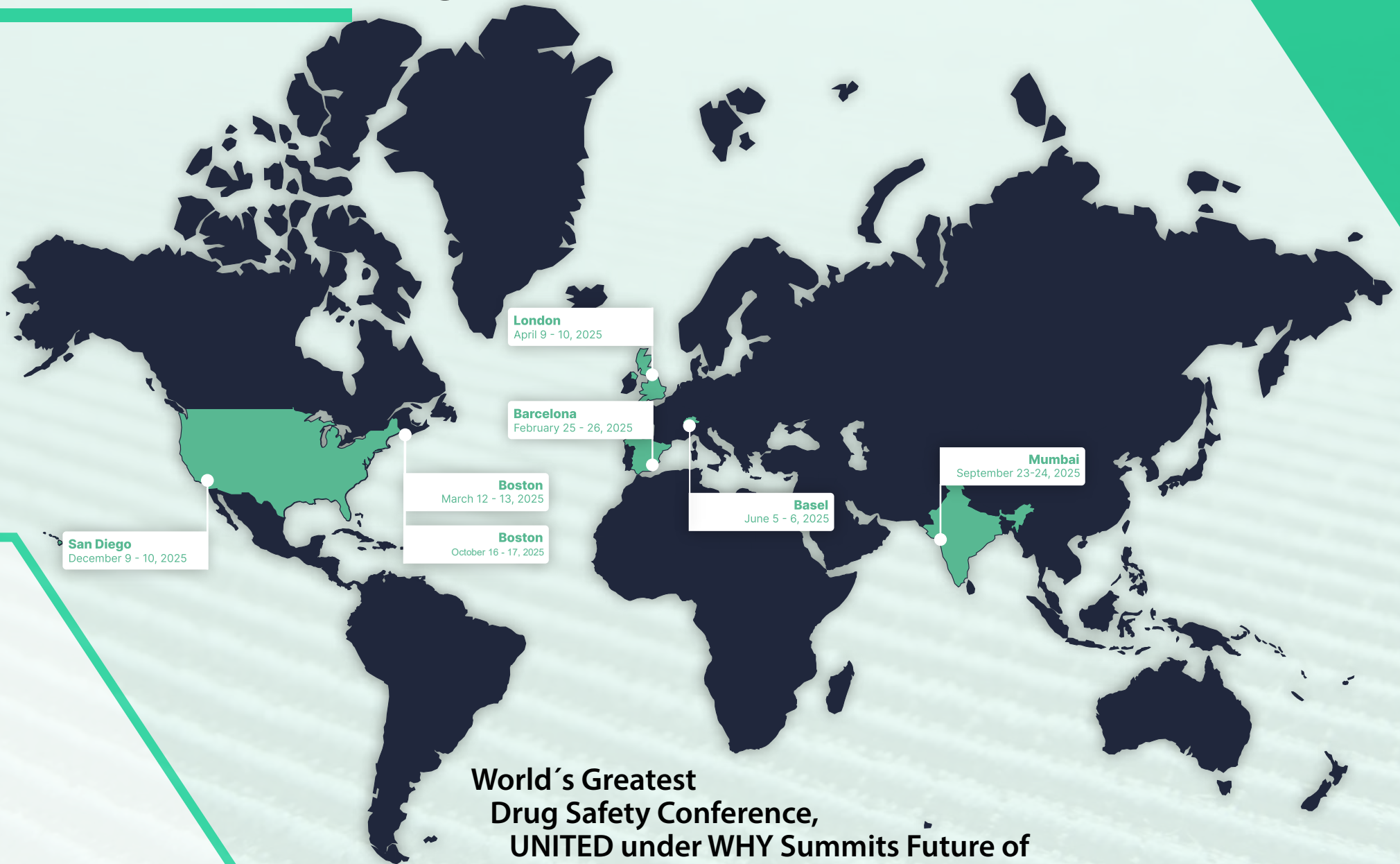
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2025 Pharmacovigilance Summits Worldwide



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

Future of Pharmacovigilance

Our prestigious American Drug Safety Summit, a cornerstone of our Pharmacovigilance World Tour.

- Join America's Leading Drug Safety Professionals
- America's Leading Drug Safety Professionals
- Gain insights into the most pressing issues facing drug safety today
- 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

- Pharmacovigilance Executives
- Regulatory Affairs Professionals
- Quality Assurance Specialists
- Drug Safety Officers
- Clinical Research Leaders
- VPs, Global Heads and Senior Directors of:
 - Drug Safety
 - Pharmacovigilance
 - 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 REMS & Risk Mitigation Strategies
- Tech Innovation: Digital Solutions for Risk Management
- Evolving REMS Programs & Regulatory Expectations
- Risk-Based Decision Making in Pharmacovigilance
- AI in REMS: 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



Dr Siva Kumar
Director Global Safety
Amgen



Andrew Mitchell
Founder
YEZA.AI



Liz Grekas
Director, Global Safety Lead
Novo Nordisk



Priyanka Chhikara
Senior Director, Head of
Pharmacovigilance Scientists
CSL



Sameen Desai
Executive Director, Head of
WorldWide Patient Safety IT
Bristol Myers Squibb



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



Kamal Shah
VP PV&DS
Veloxis Pharmaceuticals



Kal Elhoregy
Senior Director, Global
Risk Management &
Pharmacovigilance Compliance
- Global Patient Safety
Amneal Pharmaceuticals



**Karen Schriemer De
Jong**
Executive Director GPV Global
Case Management
Boehringer Ingelheim



Manjiri Nirgudkar
Director, Global Risk
Management
Bristol Myers Squibb



Kamlesh Prabhu
Director PV
BioNTech



Harsh Bhatt
Production & PV Supervisor
Aparna Pharma

Our Speakers and Panelists



**Johnson
& Johnson**

Kyle Irwin

Director REMS & Risk
Management

J&J Innovative Medicine



Apellis

Sean Green

Director, Safety Database
Strategy and Analytics at
Apellis Pharmaceuticals

Apellis



**Bristol Myers
Squibb**

Dr. Karthik Muthusamy

Senior Director, Head Expedited
Safety Reporting

Bristol Myers Squibb



**Bristol Myers
Squibb**

**Mariette Boerstool
Streefland**

SVP, Worldwide Patient Safety
Officer

Bristol Myers Squibb



amneal

Aysha Amman

Senior Director, Head of
Global Patient Safety and
Pharmacovigilance

Amneal Pharmaceuticals



Quark

Emerson Welch

VP Global Marketing

Quark

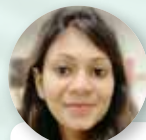


AskBio

Asif Mahmood

Vice President, Head of Medical
Safety & Pharmacovigilance

AskBio



**Johnson
& Johnson**

Meera Nagaria

Senior Data Scientist

J&J Innovative Medicine



**Johnson
& Johnson**

Shobha Rani

Senior Manager R&D, Cognitive
Automation and Analytics

Johnson & Johnson



deciphera
a member of
ONO PHARMA

Ash Higgins

Senior Pharmacovigilance
Scientist

Deciphera



sanofi

William Blumentals

Head of
Pharmacoeconomics,
Specialty Care

Sanofi



**Beam
THERAPEUTICS**

Ankit Lodaya

Senior Director
Pharmacovigilance

Beam Therapeutics

Testimonials



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."



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!"



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."



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."



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 Pharmacovigilance 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."



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."



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!"



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."

Our Valued Partners, Past & Present



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!

8:30 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

RISK IN PHARMACOVIGILANCE: ARE WE MANAGING OR MERELY REACTING?

- Current status and overview of Risk Management in PV
- Key mindset to have in approach to 2026 successfully

10:15

1ST STEP IN RISK MITIGATION

- Next-generation signal detection & risk mitigation
- Global regulatory harmonization readiness
- Working with vendors in drug safety surveillance

Priyanka Chhikara, Senior Director, Head of Pharmacovigilance Scientists, CSL

10:45 COFFEE & NETWORKING BREAK

11:15

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

Kyle Irwin, Director REMS & Risk Management, J&J Innovative Medicine

11:45

ADVANCING REMS: INNOVATION, INTEGRATION, AND THE FUTURE OF RISK MANAGEMENT

- The Evolution of REMS
- Enhancing Patient & HCP Engagement
- Measuring Success Beyond Compliance
- Future Outlook: What's Next for REMS

12:15

PANEL DISCUSSION: REMS AT A CROSSROADS — FROM TRANSITION TO TRANSFORMATION

- Lessons learned from transitions (shared systems, vendor changes, modifications)
- Balancing compliance with usability for patients and HCPs
- Leveraging technology and innovation for the future of REMS
- Building collaboration and trust among pharma, FDA, vendors, and patients

Kyle Irwin, Director REMS & Risk Management, J&J Innovative Medicine

Kal Elhoregy, Senior Director, Global Risk Management & Pharmacovigilance Compliance - Global Patient Safety, Amneal Pharmaceuticals

13:15 LUNCH & NETWORKING

14:20

ROUND-TABLE DISCUSSION: THE FUTURE OF REMS — CHALLENGES AND OPPORTUNITIES

- What's working well in REMS today, and where are the biggest pain points?
- How can we reduce burden while maintaining strong patient safety outcomes?
- Which innovations (digital tools, data, AI) will make the greatest impact?

14:50

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

Kamlesh Prabhu, Director PV, BioNTech

15:20

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

- Proactive Risk Management: Leverage partnerships to enhance early identification of safety signals, ensuring timely risk assessment and decision-making.
- Regulatory Compliance: Establish clear communication pathways and adhere to regulatory expectations, fostering transparency in adverse event reporting.
- Legal Frameworks: Develop comprehensive legal agreements that specify risk allocation and standardized operating procedures to ensure effective risk management and accountability.
- Mitigation Strategies: Implement best practices such as data protection measures, operational alignment, and regular audits to identify and manage potential risks in pharmacovigilance partnerships.

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

15:50 NETWORKING & REFRESHMENT BREAK

16:20

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)

Ankit Lodaya, Senior Director Pharmacovigilance, Beam Therapeutics

16:50

CLOSING PANEL: THE NEXT DECADE OF REMS & RISK MANAGEMENT

- What's next for REMS?
- Opportunities for innovation and global harmonization
- The role of technology in transforming patient safety

17:30 WRAP-UP & KEY TAKEAWAYS FROM DAY 1

8:30 REGISTRATION OPEN & WELCOME COFFEE

9:00 OPENING REMARKS FROM WHY SUMMITS AND THE CHAIRPERSON

9:15

OPENING ROUND-TABLE DISCUSSION: WHY ARE WE FAILING AT IMPLEMENTING NEW TECHNOLOGIES?

- Where are the biggest bottlenecks?
- Integration with legacy PV systems and clinical workflows
- Poor data quality, fragmentation, and lack of harmonization

9:45

AI IN PV: MOVE FROM HYPE TO REALITY

- Where to apply AI in PV
- Purpose: Efficiency gain vs. Capability Build
- How to set up for success: Engage full Ecosystem
- Implications for talent/employee skill set
- Case studies of AI applications at BMS

Mariette Boerstoeel Streefland, SVP, Worldwide Patient Safety Officer, BMS

10:15

HARNESSING AI AND GENAI FOR ADVANCED DRUG SAFETY INSIGHTS

- Utilizing AI and GenAI to unlock the full potential of biology for improved drug development and safety

Shobha Rani, Senior Manager R&D, Cognitive Automation and Analytics, Johnson & Johnson

10:45 COFFEE & NETWORKING BREAK

11:15

THE ROLE OF REAL-WORLD EVIDENCE IN PHARMACOVIGILANCE

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

William Blumentals, Head of Pharmacoepidemiology, Specialty Care, Sanofi

11:45

INTEGRATION OF RWD IN SIGNAL MANAGEMENT

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

Dr Siva Kumar, Director Global Safety Sciences, Amgen

12:15

SIGNAL MANAGEMENT IN EARLY VS LATE PHASE CLINICAL DEVELOPMENT: CONSIDERATIONS FOR SMALL BIOTECH

- Tools and Data Analytics
- Cross-Functional Collaboration
- Data Review Frequency

Ash Higgins, Senior Pharmacovigilance Scientist, Deciphera

12:45 LUNCH BREAK

13:50

PANEL DISCUSSION: THE FUTURE OF AI IN DRUG SAFETY

- How AI will shape PV over the next decade
- Ethical and regulatory challenges in AI adoption – global market considerations
- Balancing automation with human expertise
- You cannot implement AI agents into old structures

Panelists:

Sean Green, Director, Safety Database Strategy and Analytics at Apellis Pharmaceuticals, Apellis

Mariette Boerstoeel Streefland, SVP, Worldwide Patient Safety Officer, BMS

14:30

RESERVED FOR QUARK

15:00

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

Liz Grekas, Director, Global Safety Lead, Novo Nordisk

15:30 COFFEE & NETWORKING BREAK

16:00

PANEL DISCUSSION: CROSS-FUNCTIONAL TEAMS IN RISK MANAGEMENT (& TECHNOLOGIES ROLE)

- Aligning clinical, regulatory & safety teams for better PV outcomes
- Role of technology in streamlining collaboration
- How collaboration improves technology implementation

Panelists:

Ash Higgins, Senior Pharmacovigilance Scientist, Deciphera

Karen Schriemer De Jong, Executive Director GPV Global Case Management, Boehringer Ingelheim

17:00

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

- Innovations shaping the next era of PV
- How to stay ahead in a changing regulatory landscape
- The impact of AI, RWE, and digital transformation
- Cross-collaboration

17:30 KEY TAKEAWAYS & CLOSING REMARKS

2025 PV Summits Worldwide



- 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** 5 - 6 June, Basel
2nd Annual World Drug Safety Summit
- 5** 23 - 24 September, MUMBAI
2nd Annual Global Drug Safety & PV Outsourcing Summit
- 6** 16 - 17 October, Boston
2nd American Drug Safety - East Coast
- 7** 9 - 10 December, SAN DIEGO
3rd American Drug Safety & AI Summit 2025 - Westcoast
- 8** 11 - 12 March 2026, BOSTON
4th American Drug Safety Summit 2026 - East Coast

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

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download agenda on conference website



SPEAKING:

Jan Cizek
jan.cizek@whysummits.com

ATTENDING AND SPONSORING:

Rakesh Multani
rakesh@whysummits.com



ATTENDING AND SPONSORING:

Lubos Kusy
lubos@whysummits.com



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