WHY? SUMMITS

9 - 10 December
2025

San Diego
CA, USA

3rd American Drug Safety & AI 2025

As part of our Future of Pharmacovigilance World Tour 2025

Updated: 1 October, 2025
for the latest programe update, please download agenda on conference website

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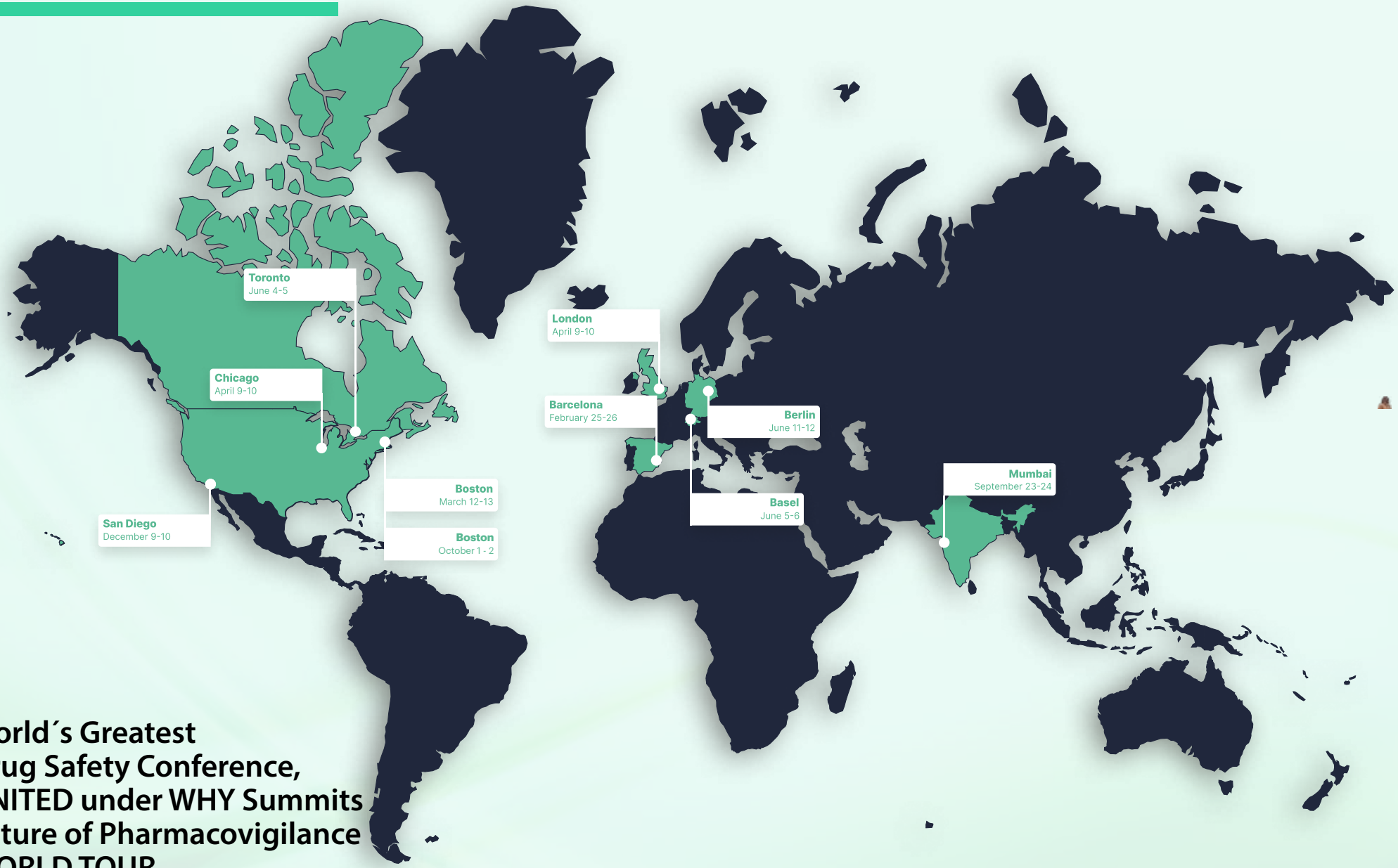
REMS Industry Consortium
Innovating Patient Safety, Mitigating Risk.

2025 Pharmacovigilance Summits Worldwide



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

Future of Pharmacovigilance

AI is already used in pharmacovigilance, but discussions often remain surface-level. As validated tools emerge, the focus shifts from if to how — ensuring transparency, compliance, and human oversight. Regulators like EMA and FDA offer guidance, yet challenges persist around validating learning systems, justifying AI-driven signals, and shaping regulations.

AI is also changing PV roles, requiring new skills and workforce retraining. Ethical concerns like bias and underrepresentation must be addressed. We invite you to explore these critical issues at the 3rd American Drug Safety & AI 2025 in San Diego.

Our newest edition to our PV World Tour 2025

- **Meet** America's top Drug Safety professionals from our 2025 World Tour
- **Taking** the discussions of AI from surface to practical applications, results and challenges
- **Discuss** the digital and innovation vision for 2026
- **What have we learnt** in 2025? Case-studies and review the will shape 2026 priorities
- **Listen** to the most crucial current topics selected & presented by industry leaders
- **Enjoy e**ducation & 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**
- **Compliance specialists**
- **Pharma IT management**
- **Safety consultants**
- **AI & ML**
- **Innovation & Digital**
- **Data & Analytics**
- **Automation**

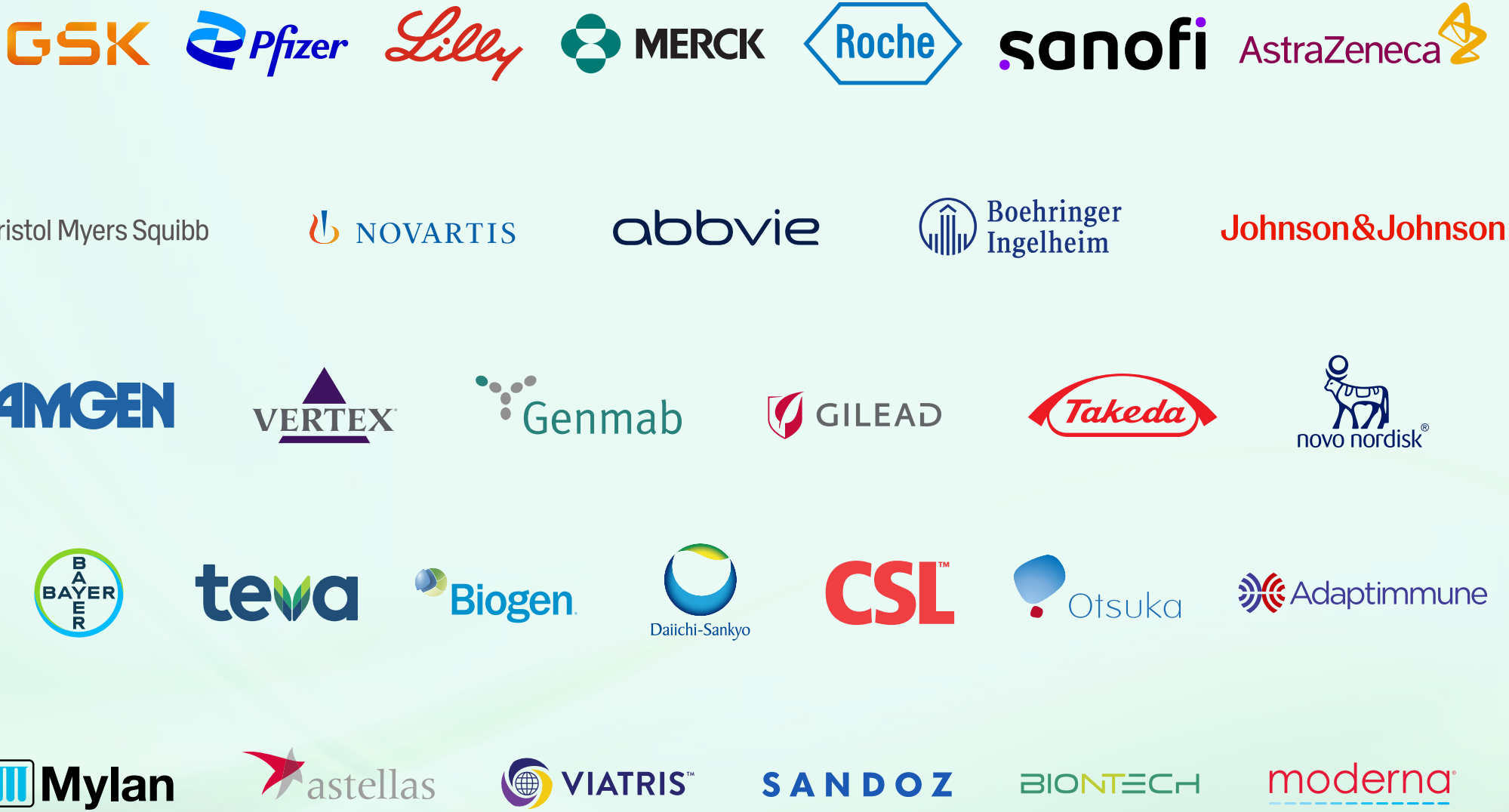
Always ask WHY?

Our San Diego concentrated knowledge-focused meeting will be focusing on topics of:

- **Cross-Departmental Data Integration for End-to-End Signal Detection**
- **Validation Frameworks for Adaptive AI/ML Models**
- **Regulatory Readiness for AI Outputs in Inspection Scenarios**
- **Digital Infrastructure for Scalable PV Automation**
- **Risk-Based Automation of ICSRs**
- **AI & RWE**
- **Cross-Validation Between Human and AI Decisions**
- **Strategies For AI Into Existing PV Frameworks**
- **Integration of AI Across Multi-Vendor PV Ecosystems**
- **Training and Upskilling the Legacy Workforce: Organizational Change Management**
- **Global Regulatory And Compliance Harmonization**
- **Harmonizing Global Data Standards for AI**
- **AI Governance Models for Safety Committees**

Industry Pioneers Attending From

WHY? SUMMITS



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 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."

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."

Meet the first onboarded speakers to 2025 edition:

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

Priyanka Chhikara
Senior Director, Head of Pharmacovigilance Scientists
CSL

Chris Carothers
Director of Responsible AI
Sanofi

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

Deepa Venkataraman
Vice President, Head of Global Patient Safety and Pharmacovigilance
Corcept Therapeutics

Eric Wesoloski
VP Quality, Regulatory Affairs and Pharmacovigilance at USAntibiotics
US Antibiotics

Scott Kelly
Senior Director, Oncology Pharmacoepidemiology and RWE
Pfizer

Subhayan Das
Director, Head- Business Insights & Technology, Patient Safety & Regulatory | Drug Development IT
Bristol Myers Squibb

Garrett Manasco
Associate Director, Clinical Artificial Intelligence
AbbVie

Mandy Gervasio
Chief Risk & Compliance Officer
Comanche Biopharma

Meet the first onboarded speakers to 2025 edition:

Bahareh Kilcoyne
R&D Quality Data Scientist
Johnson & Johnson

Emerson Welch
VP Global Marketing
Quark

Anupam Aich
Domain Lead, Product Definition, Digital Pathology Clinical AI/ML Algorithms SaMD
Roche

Slava Akmaev
Chief AI Officer, Interim Chief Operating Officer
BPGBio

Shruti Vij
Digital Transformation Lead
Takeda

Abdul Rahim
Founder & Director
Alwis Group

Amit Rakhit
Chief Medical Officer
BlueRock Therapeutics

Monica Jain
Director, R&D Data Science
J&J Innovative Medicine

Suguna Rachakonda
Vice President
Insilico Medicine

Sudhir Shandilya
Director, Digital Delivery & Operations
Sanofi

Conference Agenda

DAY 1

DAY 0 – EVENING BEFORE SUMMIT

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.

8:30 Morning Registration and early birds networking coffee

SUMMIT OPENING: PHARMACOVIGILANCE LANDSCAPE – 2025 TRENDS & CHALLENGES

9:00

OFFICIAL START OF 10TH ANNUAL PHARMACOVIGILANCE & RWE FORUM WITH OPENING REMARKS FROM WHY SUMMITS AND THE CHAIRPERSON

SUMMIT OPENING: PHARMACOVIGILANCE LANDSCAPE – 2025 TRENDS & CHALLENGES

9:10 NEXT-SEAT- MEET & GREET

9:20

REDEFINING GLOBAL DRUG SAFETY WITH AI – A STRATEGIC IMPERATIVE

- How AI is reshaping global PV frameworks
- Impact on regulatory strategy and risk management
- AI-readiness at the executive level

9:50

AI: FROM PROOF-OF-CONCEPT TO ENTERPRISE-SCALE

- Real-world deployment of NLP + RPA
- KPIs before vs after implementation
- Vendor selection & internal alignment
- In case intake & processing

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:

10:50 MORNING BREAK: COFFEE, CAKE & NETWORKING

11:20

KEYNOTE: AI APPLICATIONS FOR SAFER DRUGS, SAFER CLINICAL PRACTICES AND LOOKING INTO NEW AI REGULATION

- Early identification of adverse effects using predictive toxicology models and in silico simulations.
- AI-assisted signal detection in post-marketing surveillance—faster, more accurate trend recognition.

11:50

ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING IN PV: PRACTICAL CONSIDERATIONS

- Data Quality & Training: The Foundation for Success
- Human-in-the-Loop: Augmentation, Not Automation
- Performance Metrics: Proving AI's Value

12:20

DIGITAL INNOVATION FRAMEWORKS & CHANGE MANAGEMENT

- From Pilot to Platform: Driving Digital Innovation in a Regulated Environment

12:50 LUNCH BREAK

13:50

PANEL DISCUSSION: FUTURE PROOFING THE PV WORKFORCE

- Upskill for data literacy and AI fluency
- Emphasize cross-functional adaptability
- PV professionals will need to focus on supervising AI outputs

Conference Agenda

DAY 1

14:30

AUTOMATING THE DETECTION OF ADRS FROM DIVERSE DATA SOURCES

- Introduction and description of a new probabilistic method for causality assessment
- Automation of the tool by means of Large Language Models and predefined datasheets
- Comparing the outcomes of automated (AI driven) vs manual (human) assessment
- Exploring future use of the tool for conducting an automated semi-quantitative signals detection

15:00

GOVERNANCE, LIABILITY, AND COMPLIANCE FOR AI IN PV

- Ownership of AI decisions in safety cases
- Vendor governance and audit trails
- Data privacy, ethics, and cross-border AI compliance

15:30 Coffee & Cake Break

16:00

PANEL DISCUSSION: PV RISK MANAGEMENT

- Medical Affairs & Pharmacovigilance: Collaborating for Smarter Risk Management
- Apply machine learning for prioritization of ICSRs and flagging unexpected patterns
- Regulatory Compliance & Risk Management in the AI Era

17:00 END OF DAY 1

CLOSING REMARKS FROM THE CHAIRPERSON

Conference Agenda

DAY 2

8:50 OPENING REMARKS FROM CHAIRPERSON

9:00

ROUND-TABLE DISCUSSION: WHAT'S STOPPING YOU FROM EXTRACTING VALUE FROM EMERGING TECHNOLOGIES?

9:30

LEGAL & REGULATORY LANDSCAPE: GLOBAL WATCHPOINTS

- FDA Draft Guidance on AI in Drug Development (and future safety-specific guidance expected)
- Regulatory and ethical friction points when deploying AI in different jurisdictions

10:00

WHY AI GOVERNANCE IN PV IS MISSION-CRITICAL

- PV is a high-stakes, regulated domain—errors have patient safety and legal consequences
- AI decisions may impact ICSR triage, signal detection, RMP revisions, and compliance reporting
- Without governance, AI introduces risk: bias, drift, explainability gaps, and liability exposure

10:30 NETWORKING BREAK

11:00

STREAMLINING LOCAL AND GLOBAL LITERATURE SURVEILLANCE

- The challenges of Local Literature in Pharmacovigilance
- How AI is Transforming Literature Surveillance
- Regulatory Considerations and AI Adoption

11:30

HOW TO SELECT THE RIGHT VENDOR FOR YOUR AI PROJECTS

- The most important step for any outsourcing project is vendor selection: this is especially the case for PV and AI activities
- The key steps for vendor selection
- Vendor oversight during a project

12:30

BRIDGING THE GAP BETWEEN REMS AND GLOBAL RISK MANAGEMENT

- When and how they overlap
- Application of AI in risk management

13:00 LUNCH BREAK

14:00

LEVERAGING GENERATIVE AI IN QUALITY MANAGEMENT: ENHANCING EFFICIENCY

- Role of generative AI in PV Quality data/trend analysis
- Use prompts with relevant datasets or information in generating relevant responses using generative AI.

14:30

FROM DATA TO DECISIONS: RWE AND AI

- AI as the Engine to Unlock RWE's Full Potential
- Practical Considerations for Integration
- The Next 5 Years: What Should We Be Building Today?

15:00

PANEL DISCUSSION: THE FUTURE IS NOW – DIGITAL ECOSYSTEMS IN DRUG SAFETY

- What Does a Truly "Digital" Pharmacovigilance Ecosystem Look Like?
- Are Agencies Ready for AI-Powered Safety Monitoring?
- Barriers to Scaling AI: What's Holding Industry Back?

15:45 NETWORKING COFFEE BREAK

16:10

PRIORITIZATION OF ICSRS: MOVING BEYOND MANUAL TRIAGE

- Risk Scoring Frameworks for Case Management
- Integrating AI into enterprise risk frameworks

Conference Agenda

DAY 2

16:40

CLOSING ROUND-TABLE DISCUSSION: REFLECTIONS AND NEXT STEPS: SHAPING THE FUTURE OF PHARMACOVIGILANCE

- Wrap-up and outline actionable steps for integrating AI into future pharmacovigilance strategies.
- An open plenary discussion, with chairperson introducing the most interesting & unanswered questions. The conference will end as a free interactive networking and discussion setting goals for 2025.

17:00 CLOSING REMARKS FROM WHY SUMMITS AND THE CHAIRPERSON

Our Sponsors

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Quark

Quark empowers the world's largest pharmaceutical companies to automate the production of their highly regulated or complex documentation, so they can approve and publish it faster, and stay compliant. It enables them to accelerate regulatory approvals, release the bottlenecks around content collaboration, and get their drugs to market in record time.

Quark Publishing Platform (QPP) NextGen, the cloud-based, AI-powered component content management system (CCMS) with native XML-based structured authoring using Microsoft Word, helps pharmacovigilance teams centralize and simplify the processes involved in co-authoring and approving the PV system's critical drug safety documentation. This starts with the master file (PSMF) and traverses through all aggregated and regulatory affairs reports, including development safety update reports (DSURs), periodic adverse drug experience reports (PADERs), periodic safety update reports (PSURs), periodic benefit-risk evaluation reports (PBRERs) and risk management plans (RMPs).

Powered by Microsoft Azure OpenAI and connected with wider content and business software ecosystems such as Veeva and ArisGlobal, QPP NextGen manages every stage of the authoring and review lifecycle from end to end. PV teams increase productivity and save time by easily writing, importing, formatting and publishing complex types of variable global content to omnichannel submission outputs using structured, XML component-based authoring workflows, stringently tracking workflows in real time, driving risk reduction and safeguarding compliance.

ALWIS
A NEXTGEN SOLUTIONS

At Alwis Group, we're pioneering AI-driven solutions for the healthcare and pharmaceutical industries. Our innovative tools are transforming pharmacovigilance, enhancing drug safety monitoring, and streamlining regulatory compliance. Our suite of products includes:

ReTrans Enterprise: AI-powered literature surveillance

ReTrans Extension: Browser plugin for real-time safety data analysis

ScoMed: Intelligent medical literature scoring * ZiNex: Advanced medical document processing

ZiQuel: AI-driven quality complaint management

ZiTrack: Smart inbound receipt management

We're committed to improving patient safety and operational efficiency through cutting-edge technology. Our solutions reduce costs, minimize errors, and accelerate processes, allowing healthcare professionals to focus on what matters most – patient care.

2025 Pharmacovigilance Summits Worldwide

WHY? SUMMITS

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. 16 - 17 October, Boston
   2nd American Drug Safety Summit 2025 - East Coast
10. 9 - 10 December, SAN DIEGO
    American Drug Safety Summit 2025 - Westcoast

Our Valued Partners, Past And Present

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

Contact us

Updated: 1 October, 2025
for the latest programe update, please
download agenda on conference website

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Disclamer:
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