WHY? SUMMITS

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for the latest programe update, please download agenda on conference website

2 - 3 December, 2026

San Diego , USA

5TH AMERICAN DRUG SAFETY & AI 2026

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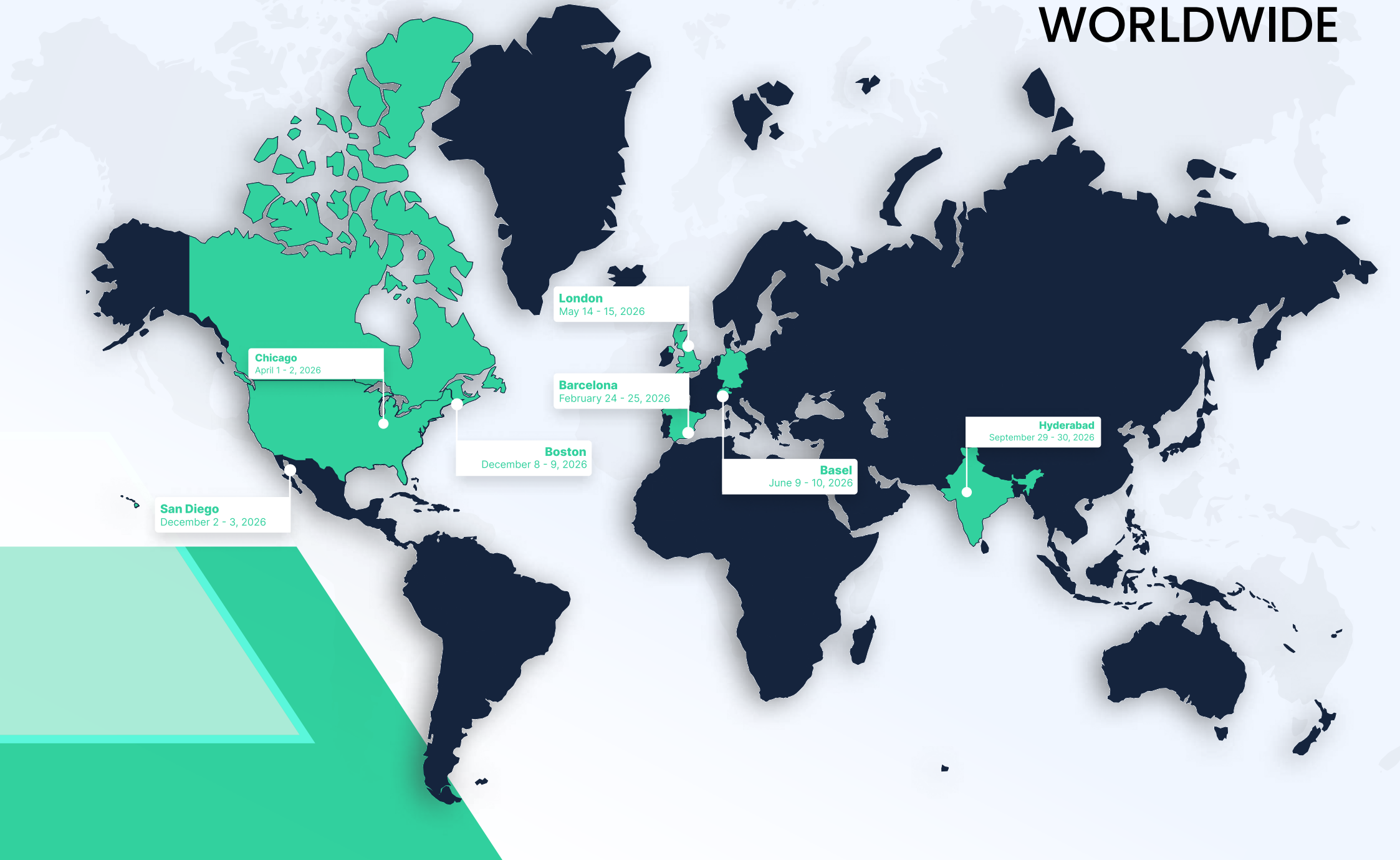
SMARTER SCIENCE. BETTER LIVES.

2026 PHARMACOVIGILANCE SUMMITS

WHY? SUMMITS

WORLDWIDE



INTRODUCTION

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 Speaker invite: 5th American Drug Safety & AI in San Diego.

OUR NEWEST EDITION TO OUR PV WORLD TOUR 2026

- Meet PV leaders leading the way, as well as pharma Tech & AI leaders that are shaping the industry
- Taking the discussions of AI from surface to practical applications, results and challenges
- Discuss the digital and innovation vision for 2027
- What have we learnt in 2026? Case-studies and review the will shape 2027 priorities
- 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
- 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:

- ENTERPRISE-LEVEL AI STRATEGIES
- 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 IMPLEMENTATION 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

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."

OUR SPEAKERS

Monica Jain
Director, R&D Data Science
Johnson & Johnson

Alok Singh
Global AI Product Manager, Analytics & Generating Insights - Product Development Informatics
Roche

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

Aparna Ahuja
Divisional Vice President Medical, Clinical and Scientific Affairs ID Rapid Diagnostics
Abbott

Abdul Rahim
Founder
Alwis Solutions

Ashish Dwivedi
Chief Customer Officer
Synapmed

Tarak Thaker
Head of Safety Systems and Reporting
BeOne

Lian Li
Senior Director Biostatistics
ScholarRock

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.

CONFERENCE AGENDA

DAY 1

8:30 MORNING REGISTRATION AND EARLY BIRDS NETWORKING COFFEE

9:00 OFFICIAL START: OPENING REMARKS FROM WHY SUMMITS

9:10

OPENING ROUND-TABLE DISCUSSION: KEY INSIGHTS

- Must-knows of the current industry status
- Key focus areas, challenges and opportunities
- What we need to discuss in the next 2 days

9:40

ENTERPRISE GRADE AI

- From Discovery to Delivery: How AI Is Rewiring the Future of Life Sciences + Healthcare
- The trust gap is real
- Strategy gap blocks ROI
- Infrastructure determines what's possible, not models

10:10

THE STRATEGIC IMPERATIVE OF AI IN PV

- PV AI as a portfolio risk & value lever, not a functional upgrade
- AI in PV is shifting from operational improvement narrative towards a portfolio-level strategic control system
- Create competitive advantages by converting PV data into predictive safety risk signals at asset level
- Integrate safety intelligence into enterprise decision-making (R&D, regulatory, market access)

10:50 MORNING BREAK: COFFEE, CAKE & NETWORKING

11:20

AI READY DATA FOR PHARMACOVIGILANCE – ENHANCING DRUG SAFETY THROUGH ADVANCED DATA PREPARATION

- AI is transforming drug safety
- Robust data foundations are essential
- Collaboration, ethics, and innovation drive progress

11:50

INDUSTRIALIZED END-TO-END ICSR PROCESSING NOT AUTOMATION PILOTS

- Moved beyond intake automation into fully orchestrated case pipelines
- How can we get to a predictable 24–72h case completion across global intake sources?

12:20

CROSS-FUNCTIONAL CONVERGENCE: CLINICAL, REGULATORY, SAFETY, AND COMMERCIAL INTELLIGENCE

- Collapsing traditional silos where clinical trial safety, post-marketing PV, and medical affairs intelligence share a unified signal system
- The enabling mechanism: unified signal system
- Cross-functional signal teams with shared accountability

12:50 LUNCH BREAK

CONFERENCE AGENDA

DAY 1

13:50

WHAT IT TAKES TO OPERATIONALIZE AI IN PV: REQUIREMENTS, PITFALLS, AND PROVEN OUTCOMES

- Enterprise-level requirements for AI: data management, upskilling, governance
- Real-world examples of AI: what worked, what didn't, and how teams overcame barriers to achieve measurable impact?
- How AI can help with FDA audit readiness
- Data challenges: Where are we going wrong?
- AI is transforming the quality, structure, and completeness of the data entering drug safety system

14:40

CREATING THE 4-LAYER AI IN PV REFERENCE MODEL

- Layer 1: Data Foundation
- Layer 2: Intelligence Layer
- Layer 3: Decision Layer
- Layer 4: Enterprise Integration Layer

15:30 COFFEE & CAKE BREAK

16:00

INSIGHT EXCHANGE: THE HUMAN SIDE OF AI IN PHARMACOVIGILANCE: REDEFINING ROLES, SKILLS, AND WORKFORCE DYNAMICS

- Upskilling: AI helps eliminate repetitive tasks, but demands new competencies from PV professionals
- A "new career path" in PV more focused on analytical and oversight roles instead of data-entry
- Cultural and structural challenges: rethinking roles, responsibilities, and retention strategies as demand for "AI-aware PV experts" grows
- The future PV expert in an AI era

17:00 END OF DAY 1 & CLOSING REMARKS FROM THE CHAIRPERSON

CONFERENCE AGENDA

DAY 2

9:00 OPENING REMARKS FROM CHAIRPERSON

9:10 ROUND-TABLE DISCUSSION

WHAT'S STOPPING YOU FROM EXTRACTING VALUE FROM EMERGING TECHNOLOGIES?

- A risk adverse culture – can it change?
- The vendor landscape fragmentation
- Integration of legacy PV systems
- Lack of clear regulatory guidance
- Unclear ownership of AI initiatives
- Slow internal validation and qualification processes

9:40

MOVING PV FROM A CASE-PROCESSING FUNCTION TO A CONTINUOUS INTELLIGENCE SYSTEM FOR PRODUCT SAFETY DECISION-MAKING

- Rebuild the data architecture as a safety intelligence layer
- Redefine human roles around exception governance
- Operationalize AI under GxP-grade lifecycle discipline

10:10

HARNESSING RWD AND AI FOR SMARTER CLINICAL DEVELOPMENT

- How do we use RWD to drive clinical development
- Is there a place for AI in curation of external/synthetic control arms

10:40 AM NETWORKING BREAK

11:10

BEYOND AUTOMATION: INTENTION-DRIVEN AI WORKFLOWS FOR THE NEXT ERA OF PHARMACOVIGILANCE

- How intention-aligned AI agents accelerate value without replicating inefficient PV processes

11:40 PANEL DISCUSSION

COMPLEXITIES OF CONNECTING AI TO ESTABLISHED ENTERPRISE ENVIRONMENTS

- Improving interfacing capabilities
- What's the best way around vendor fragmentation?
- System compatibility issues in AI modernization projects

12:30 LUNCH BREAK

13:30

HUMAN–AI OPERATING MODEL REDESIGN

- Define "Human-in-the-Loop" vs "Human-on-the-Loop" per PV activity
- Redesigning human responsibility boundaries in a regulated intelligence system
- Explicit "no-go zones" for AI autonomy in safety-critical decisions

14:00

DATA PROTECTION, PRIVACY & COMPLIANCE

- Most PV data is regulatory-compliant but not AI-usable at scale
- GDPR compliance does not equal machine-learning usability
- Cross-border data governance is now a scaling constraint

14:30

INSIGHT EXCHANGE: HOW DO WE BUILD A COMPREHENSIVE AI GOVERNANCE FRAMEWORK?

- Legal challenges and compliance strategies
- Balancing Risk Management with tech progress & innovation
- Ensuring success with AI does not compromise public health, fairness, or legal accountability
- Who is ultimately responsible for ongoing monitoring, fixes, and escalation? (Legal, PV, QA, IT or a joint AI governance committee)

15:00 COFFEE BREAK

15:30

INSIGHT EXCHANGE – SUMMARY OF THE CONFERENCE

HOW DO WE CREATE THE 4-LAYER AI IN PV REFERENCE MODEL

- Layer 1: Data Foundation
- Layer 2: Intelligence Layer
- Layer 3: Decision Layer
- Layer 4: Enterprise Integration Layer

16:30 CLOSING REMARKS FROM WHY SUMMITS

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

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WHY? SUMMITS

Attending:

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Attending and Sponsoring:

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REGISTER HERE

$2349

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"

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