

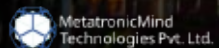


Updated: 13 February, 2026
for the latest programme update,
please download agenda on
conference website

February 24 - 25
2026

EUROPEAN DRUG SAFETY & AI 2026

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Seek less, discover better

FUTURE OF PHARMACOVIGILANCE



Our newest edition to our PV World Tour 2026

- 📌 **Meet** Europe's top Drug Safety professionals from our 2026 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** 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 steps 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 Barcelona 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 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."



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."



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!"



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."



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."



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."



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!"



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."



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."

INDUSTRY PIONEERS ATTENDING FROM



GSK  *Pfizer* *Lilly*  **MERCK**  **Roche** **sanofi** *AstraZeneca* 

 **Bristol Myers Squibb**  **NOVARTIS** **abbvie**  **Boehringer Ingelheim** **Johnson & Johnson**

AMGEN  **VERTEX**  **Genmab**  **GILEAD**  *Takeda*  **novo nordisk**

 **BAYER** **teva**  **Biogen**  **Daiichi-Sankyo** **CSL**  **Otsuka**  **Adaptimmune**

 **Mylan**  *astellas*  **VIATRIS** **SANDOZ** **BIONTECH** *moderna*

MEET THE FIRST ONBOARDED SPEAKERS

— TO 2026 EDITION



sanofi

Remco Diab

Sr. Dir. Lead Global Safety Officer Immunology & Inflammation

Sanofi



SANDOZ

Marija Simic

Director Medical Safety Team Lead, Global Patient Safety

Sandoz



ITALFARMACO

Teresa Saragoca

Technical & Regulatory Affairs Director

Italfarmco



Bristol Myers Squibb

Amer Alghabban

R&D Quality Regulatory Authority Inspection Management

Bristol Myers Squibb



Bristol Myers Squibb

Jason Burns

Director, European Data Protection Officer – EU/EEA, UK and Switzerland

Bristol Myers Squibb



wörwag PHARMA

Reinhold Schilling

Head of Global Pharmacovigilance, QPPVEU

Worwag Pharma



ORGANON

Mircea Ciuca

Global Heads Medical Safety

Organon



MERCK

Keyur Brahmbhatt

Head of Data Digital and IT (DDIT) Business Partnering for Regulatory Quality and Safety (RQS)

Merck



ALEXION

Dr. Akhilesh Chamediya

Global Medical Director Patient safety

Alexion Pharmaceuticals



INDIVIOR

Maha Lakshmi Elluri

Global Safety Director, EU/ EEA QPPV

Indivior



FAES FARMA

Edgardo Miranda

Head of International Medical Affairs

FAES Farma



SANDOZ

Dimitris Zampatis

Director Product Patient Safety (DPPS)

Sandoz



AS ArcaScience

Romain Clement

Co-founder & CEO

ArcaScience



drug.card

Dmytro Horilyk

CEO

DrugCards



ALWIS

Abdul Rahim

Founder

Alwis



Norwich Clinical Services

Dr Rajeev Patil

CEO

Norwich Clinical Services (NCS)



MetatronicMind Technologies (MMT)

Andrei Chitu

BD Consultant

MetatronicMind Technologies (MMT)



Synapmed

Ashish Dwivedi

Chief Customer Officer

Synapmed

CONFERENCE AGENDA

Day 0
23 FEB 2026

17:30 PRE-EVENT 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.



Day 1
24 FEB 2026

8:30 MORNING REGISTRATION AND EARLY BIRDS NETWORKING COFFEE

9:00

OFFICIAL START WITH OPENING REMARKS FROM WHY SUMMITS AND THE CHAIRPERSON

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

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

10:10

THE CHALLENGES OF USING AI IN PV

- Regulatory compliance and accountability
- Data privacy and confidentiality
- Validation & audit-readiness

Abdul Rahim, Founder & Director, Alwis Group

10:40 MORNING BREAK: COFFEE, CAKE & NETWORKING

11:10

AI IN PHARMACOVIGILANCE INSPECTIONS: EVIDENCE FROM EVOLVING GVP INSPECTION TRENDS AND PRACTICAL INSPECTION READINESS AND MITIGATION STRATEGIES

- **Cross-agency evolution:** How EMA, MHRA, and FDA are converging on AI governance, transparency, validation, and human oversight across PV systems.
- **Evidence from recent inspections:** What the 2025 EMA/AGES supervisory inspections and MHRA/FDA initiatives reveal about AI scrutiny in ICSR workflows, chatbots, signals, literature, and IT systems.
- **Building readiness:** Practical strategies to prepare PV systems, affiliates, vendors, and QPPVs for end-to-end AI inspection readiness.

Amer Alghabban, R&D Quality Regulatory Authority Inspection Management, Bristol Myers Squibb

11:40

HUMAN IN THE LOOP AI FOR PHARMACOVIGILANCE CASE INTAKE: FROM RAW EMAILS TO VALIDATED E2B(R3) WITH MEASURABLE QC TIME SAVINGS

- **Workflow Architecture:** Automated parsing, E2B(R3) XML generation, and two-tier QC with "back compare" for continuous learning and traceability.
- **Implementation & IT Enablement:** SaaS/AWS setup, SSO integration, and EU data residency considerations.
- **Results & Lessons Learned:** Early time study suggests case processing time reduction from ~90 minutes to ~15 minutes per case, pending formal validation.
- **Regulatory & Compliance:** Maintaining audit trails, GDPR compliance, and human oversight for regulatory accountability.
- **Scalability:** Multilingual intake, MedDRA consistency, and global regulatory readiness.

Reinhold Schilling, Head of Global Pharmacovigilance, QPPVEU, Worwag Pharma

12:10

NORWICH CLINICAL SERVICES / METATRONICMIND TECHNOLOGIES

12:50 LUNCH BREAK

13:50

PANEL DISCUSSION: NAVIGATING THE FUTURE OF PHARMA COVIGILANCE & AI

- What are the main challenges that we need to focus on?
- Managing expectations & understanding where AI adds real value in PV – what it's not
- Preparing PV organizations and leadership for change
- Defining clear success criteria for AI in PV
- What does a truly "digital" pharmacovigilance ecosystem look like?

Remco Diab, Sr. Dir. Lead Global Safety Officer Immunology & Inflammation, **Sanofi**
Marija Simic, Director Medical Safety Team Lead, Global Patient Safety, **Sandoz**
Ashish Dwivedi, Chief Customer Officer & Board Director, **Synapmed**
Dr. Akhilesh Chamediya, Global Medical Director Patient safety, **Alexion Pharmaceuticals**

14:40

RESERVED PRESENTATION

Horilyk Dmytro, CEO, **DrugCard**

15:10

ROUND-TABLE DISCUSSION: CHALLENGES IN LEVERAGING ALL BIOMEDICAL KNOWLEDGE & HOW AI CAN HELP

- Fragmented biomedical knowledge
- Case volumes are exploding & human review does not scale
- Many signals are detected statistically but lack biological plausibility
- Unstructured data overload
- How AI could leverage the full body of biomedical knowledge to enable safer drugs

Romain Clement, Co-founder & CEO, **ArcaScience**

15:40 COFFEE & CAKE BREAK

16:10

PANEL DISCUSSION: RESPONSIBLE AI IN PRACTICE: OVERSIGHT, TRANSPARENCY, AND REGULATORY ACCOUNTABILITY

- Regulatory uncertainty: difficulty in designing AI systems that are simultaneously inno-

vative, compliant, and inspection-proof across regions.

- Accountability vs automation: under-using AI to avoid perceived liability, limiting its value
- Data bias and representativeness
- End-to-end transparency
- Data protection
- Governance gaps between functions

Edgardo Miranda, Head of International Medical Affairs, **FAES Farma**

Teresa Saragoca, Technical & Regulatory Affairs Director, **Italfarmco**

Jason Burns, Director, European Data Protection Officer - EU/EEA, UK and Switzerland, **Bristol Myers Squibb**

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

17:00 NETWORKING COCKTAIL RECEPTION



8:50 OPENING REMARKS FROM CHAIRPERSON

9:00

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

9:30

BY 2030... WHAT HAPPENS IF RA, PV & AI STILL DON'T SPEAK TO EACH OTHER?

- Barriers that impede effective collaboration between RA, PV, and AI functions
- The best-case Scenario vs the worst-case scenario
- Challenges & Needs

Teresa Saragoca, *Technical & Regulatory Affairs Director, Italfarmco*

10:00

DATA PROTECTION, COMPLIANCE, AND PRIVACY STRATEGY

- Establishing data protection and compliance frameworks across clinical, safety, and commercial activities.
- Managing privacy strategy for innovation, contracts, and industry collaboration.

Jason Burns, *Director, European Data Protection Officer - EU/EEA, UK and Switzerland, Bristol Myers Squibb*

10:30 NETWORKING BREAK

11:00

PANEL DISCUSSION: DEMYSTIFYING AI IN PHARMACOVIGILANCE

- Moving beyond AI hype and focus on what truly works in the real world.
- Unpacking common misconceptions around automation, human oversight, validation, data quality, and compliance
- Emphasizing the importance of open ecosystems, strong governance, and clear accountability

Ashish Dwivedi, *Chief Customer Officer & Board Director, Synapmed*

Mircea Ciuca, *Global Heads Medical Safety, Organon*

11:50

ADVANCING CELL THERAPY SAFETY WITH REAL-WORLD DATA: FROM SIGNAL DETECTION TO PROACTIVE RISK MITIGATION

- Purpose of RWD: Extend safety surveillance beyond trials to diverse, real-world populations and care settings across the cell therapy lifecycle.

- Signal Detection: Improve early identification of rare, delayed, and context-specific toxicities using fit-for-purpose cohorts and advanced analytics (e.g., NLP, temporal methods).
- Benefit-Risk Assessment: Strengthen evidence with external comparators and longitudinal outcomes, enabling credible, subgroup-aware evaluations.
- Proactive Mitigation: Translate insights into risk models and learning-health-system feedback loops to optimize patient selection, monitoring, and intervention pathways.
- Data Quality and Methods: Ensure completeness, timeliness, provenance, standardized terminologies, prespecified protocols, confounding control, and sensitivity analyses.
- Regulatory Alignment: Meet expectations for fit-for-purpose sources, traceable and reproducible methods, and early engagement aligned to RWD/RWE, pharmacovigilance, and PASS guidance.

Dr. Akhilesh Chamediya, *Global Medical Director Patient safety, Alexion Pharmaceuticals*

12:30 LUNCH BREAK

14:00

CREATING THE DIGITAL AND DATA INITIATIVES TO DRIVE AI TRANSFORMATION

- Data requirements for AI implementation
- Harnessing technology for real-world impact
- How it's helped in regulatory quality

Keyur Brahmhatt,

Head of Data Digital and IT (DDIT) Business Partnering for Regulatory Quality and Safety (RQS),

Merck

14:30

PANEL DISCUSSION 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

CONFERENCE AGENDA

Day 2
25 FEB 2026

15:00

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.

15:45 NETWORKING COFFEE BREAK

16:40

CLOSING ROUND-TABLE DISCUSSION: REFLECTIONS AND NEXT STEPS

- 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 2026.

17:00 CLOSING REMARKS FROM WHY SUMMITS AND THE CHAIRPERSON

OUR PAST PARTNERS



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: 13 February, 2026
for the latest programme update,
please download agenda on
conference website



Attending:



Jan Cizek
jan.cizek@whysummits.com

Attending and Sponsoring:



Lubos Kusy
lubos@whysummits.com

Attending and Sponsoring:



Rakesh Multani
rakesh@whysummits.com

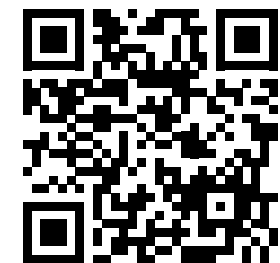
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