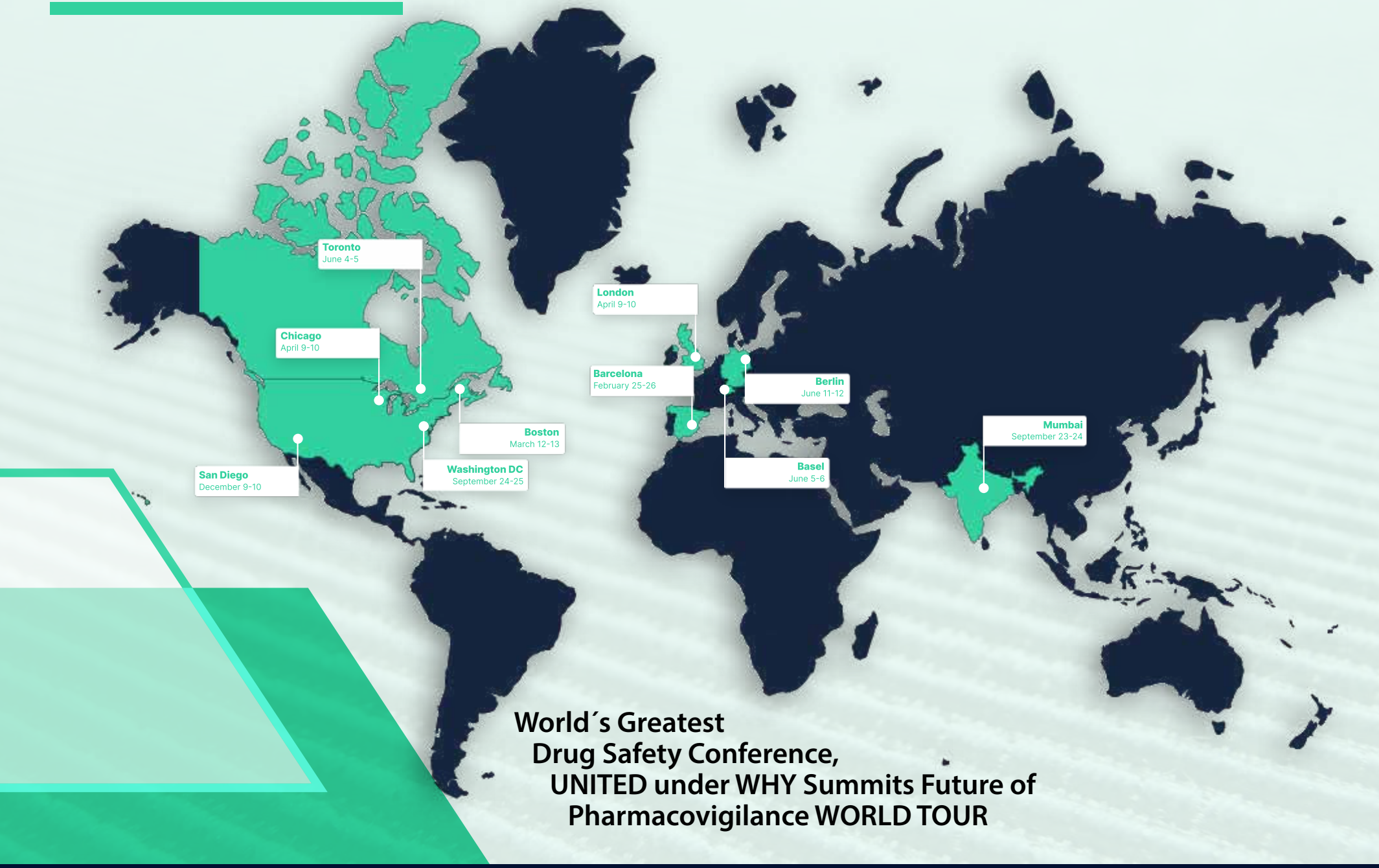
Updated: 7 March, 2025
for the latest programe update, please
download agenda on conference website

American Drug Safety Summit

Boston | Massachusetts
WYNDHAM Boston Beacon Hill
5 Blossom Street, Boston, MA 02114

12th - 13th March | 2025

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
- **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

- **Drug safety & Pharmacovigilance executives**
- **Heads of global safety programs**
- **Benefit-Risk assessment management**
- **Medical affairs management**
- **Patient safety management**
- **Compliance specialists**
- **Post-market researchers**
- **PV auditors**
- **Regulatory affairs directors**
- **Vendor Management & Outsourcing**
- **Pharma IT management**
- **Safety consultants**

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:

- **Current Trends and Challenges in PV**
- **Pharmacovigilance Technology Journey**
- **Enhancing PV and Drug Safety Operations**
- **Building Trust, Ensuring Safety**
- **New Directions in Benefit-Risk Assessments**
- **Driving Patient Centricity**
- **Risk-Based Thinking in Audit Process**
- **Offshoring PV Solutions**
- **Transforming Pharmacovigilance**
- **Fundamentals of Engaging Learning**
- **AI in Drug Safety Monitoring**
- **Integrating Data Sources**
- **Process and System Optimization**

Gold Partners

PrimeVigilance, an Ergomed company, is delivering global solutions for clinical safety and post-marketing pharmacovigilance and medical information. PrimeVigilance provides pharmacovigilance solutions to over 300 clients who distribute their products worldwide. PrimeVigilance manages a global Pharmacovigilance system with a choice of leading drug safety databases, stretching to more than 100 countries.

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. 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.

Silver Partners

4C Pharma Solutions is a comprehensive global healthcare solutions company specializing in end to end of Pharmacovigilance, Materiovigilance, Medical Information Call Center, Hosting, Regulatory Affairs, Medical Affairs, CDM & Staff Augmentation.

Veeva is the global leader in cloud software for the life sciences industry.

Veeva Safety applications operate as a unified pharmacovigilance system on a single cloud platform to maximize operational efficiencies and improve patient safety. Automating data flow and simplifying PV processes, Veeva Safety delivers solutions to manage case processing from intake to submissions, PSMF, pharmacovigilance agreements, RMPs, aRMMS, and more.

IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions, and clinical research services to the life sciences industry. IQVIA creates intelligent connections across all aspects of healthcare through its analytics, transformative technology, big data resources and extensive domain expertise. IQVIA Connected Intelligence™ delivers powerful insights with speed and agility — enabling customers to accelerate the clinical development and commercialization of innovative medical treatments that improve healthcare outcomes for patients.

Biologit MLM-AI is a state-of-the-art platform for monitoring scientific literature to identify adverse events and emerging risks throughout a product's lifecycle, from clinical development to post-marketing. It combines a flexible workflow with a unified global and local scientific database, enhanced by unique AI-driven screening and productivity tools.

Quark knows content. The company revolutionized desktop publishing and provides content automation, intelligence and design software for end-to-end content lifecycle management. Quark helps to modernize content ecosystems so they can create complex print and digital layouts, automate omnichannel publishing of mission-critical documents, and analyze production and engagement insights for the greatest return on their content investments.

Strategic Partner

Veridat brings together a range of capabilities to help clients in response to a changing environment, reduce risk in response to growing complexity, and improve the processes and systems that protect brands, build trust, and add business value. Our flagship product, Bench™, is a lightweight, flexible, and easily implemented rendering data immutable and verifiable. Registered participants will be offered a free trial of 5,000 transactions to create their own environment and experience, to be able to test & verify the increased effectiveness of data management value chain.

Panel Partner

Advity Research provides an integrated clinical research portfolio, which includes Bioavailability/Bioequivalence (BA/BE) services, clinical trial services, and pharmacovigilance services; supporting Pharma & Biotech companies with Medical information call centre, Literature search, Database, Signal Management, Case processing and Aggregate reporting solutions.

Industry Pioneers Attending From

WHY? SUMMITS

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

Past Partners

PREVAIL INFOWORKS · ALWIS · CLINEVO · COGNIFAI Automate | Innovate | Accelerate · ETHICARE Clinical Trial Services · ennov

Syneos Health · drugcard · TriNetX · PHARMORA

Testimonials

Christine Clearwater
Manager, Safety Operations and Vendor Management
Baxter, Global Patient Safety
★★★★★
"Unlike some other similar events, I found relevance in every session within your conference. The content was neither too simplistic nor too advanced. The participants and presenters provided a diverse view of the issues that are present for most in this industry."

Erika Barbarosie
Associate Director PV Compliance
Gilead Sciences
★★★★★
"A huge shout out to Why Summits for the terrific organization, bringing all these talented people together. Great minds, great conversations, great topics. Buckling up for the next 😄."

Sameer Thapar
Assistant Professor & Advisor, Drug Safety and Pharmacovigilance
Rutgers University
★★★★★
"Great dialogue on key issues. Everyone shared truthful insight and did not hold back, even on negative experiences."

Daniel Naranjo
Global Safety Lead, Global Patient Safety Evaluation
Takeda
★★★★★
"Loved it. It was very practical and provided valuable insight into practical methods that are actionable for patient safety."

Lewis Atkinson
Director of Business Development for PV Drug Safety Technology
IQVIA
★★★★★
"I have thoroughly enjoyed the past 2 days of networking with my colleagues and industry professionals. Thank you to Why Summits for wonderful organisation! I look forward to Basel later in the year!"

Souhail Debaghi
Director of Sales
TriNetX
★★★★★
"Really enjoyed the Pharmacovigilance & RWE Forum by Why Summits! What I loved most, is how friendly, collaborative and intimate the PV community really is. This is of course great to see, as a vendor, but more so a potential patient receiving the outputs of this heroic work!"

Kyle Derstine
Principal Product Leader, Digital Transformation
Genentech Product Development
★★★★★
"I just think what's also wonderful is that it's very local organized conferences but people fly in from everywhere and so you do get a really good representation across like 40 different companies – big, small, medium size and that's trully where the value of this collective is."

Cláudia Meneses
Senior Pharmacovigilance Officer
Sanofi
★★★★★
"Thanks to the 9th Global Pharmacovigilance & RWE Forum speakers, for sharing their knowledge and experience. It was a great first Pharmacovigilance conference and a good chance to meet more like-minded people in the industry."

Vijay Singh
Associate Director, Product PV Device Digital Safety
UCB
★★★★★
"Thank you Why Summits for the opportunity to share my thoughts on Advancements & Challenges in Signal Detection. It was great to share my thoughts along with other panelists."

Speakers and Panelists

Alison Purdon
Director, MAP & Safety Partnering, US Patient Safety
Genentech

In the Chair

Andrew Mitchell
CEO / Founder
YEZA.ai

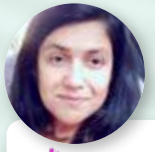
Gigi Atalla
Vice President, Head of Global Drug Safety & Pharmacovigilance
Genmab US, Inc

Israel Gutierrez
Chief Medical Officer
TLR Therapeutics Inc

Karthik Muthusamy
Sr Director, Head of Expedited Safety Reporting
Bristol Myers Squibb

Khaudeja Bano
Vice President Combination Product Quality
Genentech/Roche

Ashraf Youssef
Functional Area Lead, Patient Safety and Pharmacovigilance
Takeda Pharmaceuticals



Manjiri Nirgudkar
Director, Global Risk Management
BMS

Marissa StLouis
Safety Partnering Lead
Genentech

Mina Ebeid
Director Drug Safety and Pharmacovigilance Scientist
Genmab US, Inc

Robert Huber
Co-founder and Chief Product Officer
Veridat

Scott Fonseca
VP, Managing Director, Integrated Safety
IQVIA

Peder Seglund
Global Head of Business Development
4C Pharma Solutions

Speakers and Panelists

Christina Kim
Senior Director, Safety Strategy
Veeva Systems

Karthik Babu P S
CHC Global PV Operations Head
Opella

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

Katarina Ilic
Expert Consultant

Vasudev Sureddy
Executive Director
Advity Research

Jacqueline Gerena
Director Risk Management Strategy
Johnson & Johnson

Nicole Baker
CEO
Biologit

Nina Patel Lahanis
VP, Safety Data Management
PrimeVigilance

Jamie Wilkins
Head Risk Management Center of Excellence, Worldwide Safety
Pfizer

Abdul Rahim
CEO & Founder
Alwis Solutions

Christine Hunter
Senior Consultant, Veeva Safety
Veeva Systems

Liz Grekas
Global Safety Lead
Novo Nordisk

Sean Green
Director, Safety Database Strategy and Analytics
Apellis Pharmaceuticals

Conference Agenda

DAY 1

DAY 0 – NIGHT BEFORE THE EVENT

5:30PM 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!

8:30AM OPENING REMARKS & ICEBREAKER

Start the conference on a positive note with warm welcoming remarks from our distinguished hosts. Dive into an engaging icebreaker activity designed to foster connections, spark conversations, and set the tone for a collaborative and productive event. Get ready to break the ice and kick off our conference with energy and enthusiasm.

CURRENT TRENDS AND CHALLENGES IN PV

8:35AM

PRESENTATION: Enhancing Data Effectiveness and Risk Management through Cross-Functional Collaboration in Pharmacovigilance

- Integrated Data Sharing: Strengthening collaboration between Quality, Clinical, Operations, Manufacturing, and Supply Chain to streamline data collection and reporting.
- Proactive Safety Monitoring: Leveraging real-time data and advanced analytics to detect and address emerging safety signals across departments.
- Regulatory Compliance & Risk Management: Ensuring alignment with evolving pharmacovigilance regulations to maintain data integrity and mitigate risks.
- Optimized Decision-Making: Using integrated data systems to enable faster, more informed responses to safety concerns and regulatory requirements.

Khaudeja Bano, *Vice President Combination Product Quality,* **Genentech/Roche**

9:00AM

ENHANCING PV AND DRUG SAFETY OPERATIONS: Effective and Efficient Control

- Revolution in operational efficiency, safety reporting reliability, responsiveness, and overall regulatory compliance
- Robust dynamic controls for Pharma and Biotech companies in the entire PV lifecycle
- Harmonization and system integration through interoperability and transparency lawyers

Robert Huber, *Co-founder and Chief Product Officer,* **Veridat**

9:15AM

OPENING PANEL DISCUSSION: SHAPING THE FUTURE OF PHARMACOVIGILANCE:

- Challenges & Opportunities for Gen AI in Medical Safety teams in PV
- Quality Optimization of PV case processing using AI
- Setting up new PV Department – CRO, In-House or Hybrid
- Financial constraints in launching new PV initiatives with ever shrinking budgets
- Potential of emerging technologies in improving PV process

Moderator:

Karthik Babu P S, *CHC Global PV Operations Head,* **Opella**

Panelists:

Andrew Mitchell, *CEO / Founder,* **YEZA.ai**

Vasudev Sureddy, *Executive Director,* **Advity Research**

Ashraf Youssef, *Functional Area Lead, Patient Safety and Pharmacovigilance,* **Takeda Pharmaceuticals**

9:45AM

PRESENTATION: REMS Industry Consortium: Driving Innovation and Standardization in REMS

Collaboration is the key to progress - so who's leading the charge in REMS?

The REMS Industry Consortium (RIC) is by bringing together key stakeholders to drive innovation and standardization in the REMS space. In this session, you'll gain insight into the consortium's structure - from its dynamic work groups to its diverse membership levels - while showcasing its achievements, upcoming initiatives, and the value it delivers to members and the industry.

Discover the impact this collective effort is making and why its work matters. Don't miss this opportunity to learn, engage, and find out how you can be part of the change!

Jacqueline Gerena, *Director Risk Management Strategy,* **Johnson & Johnson**

10:15AM COFFEE & NETWORKING

Conference Agenda

DAY 1

10:45AM

KEYNOTE: Building Trust, Ensuring Safety: Establishing Strong Commercial Partnerships for Effective Digital Pharmacovigilance

- Digital Engagement and Oversight: Implement a comprehensive pharmacovigilance oversight system for digital engagement strategy across all digital channels, including social media and influencer partnerships based on existing regulatory requirements. This approach allows us to enhance patient outreach, education, and support while maintaining rigorous oversight to ensure accurate and compliant communications.
- Establishing strong partnerships with the commercial organization: Learning our Commercial colleagues' businesses, to co-create compliance solutions that integrate Safety requirements with their goals.
- Leveraging Innovative Tools for Enhanced User Experience: Enabling partners to focus on strategic work by streamlining the identification of adverse events with innovative technology to enhance user experience.

Alison Purdon, *Director, MAP & Safety Partnering, US Patient Safety,* **Genentech**
Marissa StLouis, *Safety Partnering Lead,* **Genentech**

PV TRANSFORMATION; RISK MINIMIZATION STRATEGIES AND RMP PLANS

11:15AM

TRANSFORMING PHARMACOVIGILANCE: Innovative Solutions to Rebuild Trust and Avert a Healthcare Crisis

- Elevate Transparency and Build Trust by implementing comprehensive drug information platforms that provide transparent clinical trial data and real-time adverse reactions reporting.
- Strengthen Patient Engagement in Research by developing patient-centric research platforms that involve patients directly in the research process, from clinical trials to post-marketing surveillance, ensuring their voices shape future drug development and safety monitoring.
- Ensure Data Security and Privacy by implementing blockchain-based health records systems to ensure secure, transparent, and patient-controlled management of health data, enhancing trust and data security.

Moderator:
Gigi Atalla, *Vice President, Head of Global Drug Safety & Pharmacovigilance,* **Genmab US, Inc &**
Panelists:
Khaudeja Bano, *Vice President Combination Product Quality,* **Genentech/Roche**
Robert Huber, PhD, *Co-founder and Chief Product Officer,* **Veridat**

11:45AM

Driving Patient Centricity through Pharmacovigilance and Risk Management

- Integration of Real-World Data: Challenges and benefits of integrating real-world data into predictive risk assessment tools.
- Real-world challenges organizations face when implementing advanced tools.
- AI and Machine Learning applications in predictive risk assessment.
- Integration of Big Data analytics for real-time monitoring.

Scott Fonseca, *VP, Managing Director, Integrated Safety,* **IQVIA**

12:15PM LUNCH

REGULATORY, OPERATIONS AND REMS IMPROVEMENTS

1:15PM

KEYNOTE: Safety Biomarkers in Drug Development: Current Trends and Regulatory Insights

- The Evolving Role of Safety Biomarkers – Understanding the significance of safety biomarkers in early drug development, clinical trials, and post-market surveillance.
- Regulatory Landscape & Guidelines – Overview of FDA, EMA, and ICH guidelines for safety biomarker qualification and their impact on drug approval processes.
- Innovative Biomarker Strategies – Advances in predictive and translational safety biomarkers, emerging technologies, and case studies from recent drug development programs.
- Challenges & Future Perspectives – Addressing validation hurdles, standardization issues, and the future role of AI and multi-omics in safety biomarker research.

Katarina Ilic, *Expert Consultant*

1:45PM

PRESENTATION: How offshoring PV Solutions can increase efficiencies and reduce risks

- Cost Efficiency and Scalability
- Access to Specialized Expertise
- Operations and Faster Turnaround
- AI, ML, NLP applications for PV

Peder Seglund, *Global Head of Business Development,* **4C Pharma Solutions**

Conference Agenda

DAY 1

2:15PM

PANEL DISCUSSION: Global Patient Safety and Risk Management Compliance

The latest trends and methodologies in REMS, considering advancements in data analytics, real-world evidence, and patient-reported outcomes.

- Integration of Compliance within Pharmacovigilance and Risk Management disciplines
- Pharmacovigilance & Risk management inspection readiness
- Auditable systems and continuous monitoring - maintain robust records to support regulatory inspections
- FDA REMS Reporting Inspection areas of focus and consideration
- FDA PADE Inspection Compliance Program areas of focus and consideration
- Utilization of AI – Progress toward patient safety and risk minimization

Moderator:

Kal Elhoregy, *Senior Director, Global Risk Management & Pharmacovigilance Compliance,* **Amneal Pharmaceuticals**

Panelists:

Manjiri Nirgudkar, *Director, Global Risk Management,* **BMS**

Jacqueline Gerena, *Director Risk Management Strategy,* **Johnson & Johnson**

Katarina Ilic, *Expert Consultant*

Jamie Wilkins, *Head Risk Management Center of Excellence, Worldwide Safety,* **Pfizer**

2:45PM NETWORKING BREAK

3:15PM

KEYNOTE: Streamline Risk Management and Minimization and Gain Global Oversight

- Global Oversight: Improve oversight of core and local risk management plans (RMPs) and associated risk minimization measures.
- Operational Efficiency: Leverage core RMPs for local versions, and streamline management to ensure teams are always using the correct product/market plan.
- Stakeholder Collaboration: Work seamlessly across global/local safety teams and affiliates, and monitor compliance of RMP and aRMM commitments.

Christina Kim, *Senior Director, Safety Strategy,* **Veeva Systems**

Christine Hunter, *Senior Consultant, Veeva Safety,* **Veeva Systems**

3:45PM

KEYNOTE: Strategic Partnerships in Pharmacovigilance: Business, Legal and Regulatory Domains

- The significance of pharma partnerships and the contribution of Pharmacovigilance
- Health authorities and regulatory expectations from partnerships
- Legal agreements and documents roles in supporting successful partnerships
- Risks for pharmacovigilance partnerships and best practice to mitigate the risks

Ashraf Youssef, *Functional Area Lead, Patient Safety and Pharmacovigilance,* **Takeda Pharmaceuticals**

4:15PM

PANEL SESSION: Stability of Drug Safety Systems

- Streamlining PV Processes: Implementing standardized workflows and automated systems to enhance efficiency and ensure compliance with regulatory standards.
- Robust Quality Assurance Frameworks: Developing comprehensive QA protocols to monitor and improve data accuracy, case management, and reporting practices.
- Continuous Process Improvement: Utilizing key performance indicators (KPIs) and regular audits to identify gaps and drive ongoing enhancements in safety and quality systems.

Moderator:

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

Panelists:

Karthik Muthusamy, *Sr Director, Head of Expedited Safety Reporting,* **Bristol Myers Squibb**

Alison Purdon, *Director, MAP & Safety Partnering, US Patient Safety,* **Genentech**

Liz Grekas, *Global Safety Lead,* **Novo Nordisk**

4:45PM THAT´S A WRAP

4:50PM NETWORKING COCKTAIL RECEPTION

Conference Agenda

DAY 2

DATA UTILIZATION, A.I. AND M.L. IN PHARMACOVIGILANCE

8:30AM

PRESENTATION: FOUNDATIONAL CONCEPTS AND APPLICATIONS OF AI IN DRUG SAFETY MONITORING

- Internal safety tool key features
- Basics of InferBERT Modeling
- Foundational concepts in establishing an AI tool
- Human oversight and management

Gigi Atalla, *Vice President, Head of Global Drug Safety & Pharmacovigilance,* **Genmab US, Inc &**
Mina Ebeid, *Director Drug Safety and Pharmacovigilance Scientist,* **Genmab US, Inc**

9:00AM

PANEL DISCUSSION: INTEGRATING DATA SOURCES INTO A COMPREHENSIVE PV SYSTEM

- Getting the best possible data.
- Leveraging data beyond spontaneous reports.
- Real world data or big data - What role do they play?
- Integrating in daily lives of PV scientists.

Moderator:
Khaudeja Bano, *Vice President Combination Product Quality,* **Genentech/Roche**
Panelists:
Mina Ebeid, *Director Drug Safety and Pharmacovigilance Scientist,* **Genmab US, Inc**

9:30AM

CASE STUDY: Optimizing Quality of Deliverables with PV Vendors

- Rigorous Vendor Selection and Compliance: The selection of pharmacovigilance vendors was based on a thorough evaluation of their regulatory compliance, industry certifications, and capacity to meet global pharmacovigilance standards, ensuring high-quality safety reporting and risk management.
- Enhanced Communication and Knowledge Sharing: Regular and structured communication channels between the pharmacovigilance vendors and the internal team facilitated the exchange of knowledge, timely updates on safety process documents, and best practices, ensuring prompt detection and resolution of safety issues.
- Real-Time Data Analysis and Reporting Efficiency: Leveraging safety monitoring tools and analytics platforms enabled continuous tracking of adverse events, optimizing the timeliness and accuracy of pharmacovigilance reporting, which led to more efficient regulatory submissions and better patient safety outcomes.

Nina Patel Lahanis, *VP, Safety Data Management,* **PrimeVigilance**

10:00AM COFFEE & NETWORKING

EFFICACY AND SAFETY; A.I. AND M.L. IN PHARMACOVIGILANCE

10:30AM

KEYNOTE: Challenges in finding new drug regimens for TB

- Balancing Efficacy and Safety in Drug Development – New TB drugs must be potent enough to combat resistant strains while minimizing toxicity and adverse effects, particularly given the long duration of treatment.
- Drug Interactions and Patient Vulnerability
- Long-Term Safety Monitoring & Regulatory Approval

Liz Grekas, *Global Safety Lead,* **Novo Nordisk**

11:00AM

KEYNOTE: Accelerating Patient Safety: Leading with Evidence, AI and Scientific Expertise.

- Utilization of patient records and healthcare databases.
- How data collection supports early detection of potential safety issues.
- Minimizing the collection of unnecessary patient information.
- Robust data collection for identifying adverse drug reactions (ADRs) and ensuring the safety of pharmaceutical products.

Nicole Baker, *CEO,* **Biologit**

Conference Agenda

DAY 2

11:30AM

PANEL DISCUSSION: THE EVOLUTION OF AI IN PHARMACOVIGILANCE: OPPORTUNITIES AND CHALLENGES

- Discussing the ways AI can revolutionize pharmacovigilance processes and improve patient safety. Establishing foundation for AI-enabled business
- Addressing potential challenges, such as data quality, model interpretability, and regulatory considerations, in integrating AI into pharmacovigilance practices.
- Sharing insights on successful strategies for implementing AI in pharmacovigilance, considering organizational readiness and regulatory landscape.
- Regulatory Frameworks: discussing current regulatory frameworks and guidelines governing the use of AI in pharmacovigilance.

Moderator:
Andrew Mitchell, *CEO / Founder,* **YEZA.ai**
Panelists:
Karthik Babu P S, *CHC Global PV Operations Head,* **Opella**
Gigi Atalla, *Vice President, Head of Global Drug Safety & Pharmacovigilance,* **Genmab US, Inc**
Sean Green, Director, *Safety Database Strategy and Analytics,* **Apellis Pharmaceuticals**

12:00PM LUNCH BREAK AND NETWORKING

PATIENT CENTRICITY IN PHARMA – INCLUSIVITY IN SAFETY AND AI INNOVATION

1:30PM

KEYNOTE: Revolutionizing PSPV with Futuristic Gen AI-Powered Real-World Data

- Next-Generation AI & LLM Digital Platform
- AI-Driven Data Insights
- Trend & Pattern Identification
- Comparative Analysis

Abdul Rahim, *CEO & Founder,* **Alwis Solutions**

2:00PM

PANEL DISCUSSION: INNOVATION IN SIGNAL DETECTION, PHARMACOVIGILANCE AND AI

- State of innovations in the area
- Connecting the dots to work for your organization
- Current AI guidelines are they up to speed?
- How organizations move the AI implentation and success

Moderator:
Israel Gutierrez, *Chief Medical Officer,* **TLR Therapeutics Inc**
Panelists:
Manjiri Nirgudkar, *Director,* **Global Risk Management, BMS**
Christina Kim, *Senior Director,* **Safety Strategy, Veeva Systems**

2:30PM COFFEE & NETWORKING

3:00PM

KEYNOTE: BEST PRACTICES in SUSAR NOTIFICATIONS TO INVESTIGATORS

- Expedited Reporting Requirements: Understanding the Global Regulatory Landscape (IND Safety Reports vs other SUSARs)
- Navigating the Challenges of SUSAR Notifications to Investigators
- Best Practices – Leveraging Technology in automation and centralization of systems, Fostering strong collaboration between sites and sponsors; Ongoing oversight and compliance monitoring.

Karthik Muthusamy, *Sr Director, Head of Expedited Safety Reporting,* **Bristol Myers Squibb**

Conference Agenda

DAY 2

3:30PM

ROUNDTABLE DISCUSSIONS 1: IMPROVING PHARMA-HCP-PATIENT COMMUNICATION IN PV

- Effective Communication: Utilizing diverse channels for reaching HCPs and patients. Implementing tailored approaches for different stakeholders.
- Engagement Strategies: Foster collaborative relationships with HCPs. Involve patient advocacy groups to enhance engagement.
- Material Distribution: Ensure timely and accessible safety information. Utilize digital platforms for distribution of materials.
- Education and Training: Provide HCP training on adverse event reporting. Educate patients on the importance of reporting.

Roundtable Moderator:
Alison Purdon, *Director, MAP & Safety Partnering, US Patient Safety,* **Genentech**

ROUNDTABLE DISCUSSIONS 2: Enhancing PV Organization and System Processes for Seamless Cross-Functional Collaboration

- Optimizing Pharmacovigilance Systems & Workflows – Streamlining case management, signal detection, and regulatory reporting to improve efficiency and compliance.
- Cross-Functional Team Synergy – Strengthening collaboration between PV, regulatory, clinical, and commercial teams to enhance data sharing and decision-making.
- Leveraging Technology & Automation – Exploring AI, automation, and centralized PV platforms to improve risk management and operational effectiveness.

Roundtable Moderator:
Sean Green, Director, *Safety Database Strategy and Analytics,* **Apellis Pharmaceuticals**

ROUNDTABLE DISCUSSIONS 3: TECHNOLOGY IMPLEMENTATION IN PHARMACOVIGILANCE DEPARTMENTS: ADVANTAGES, CHALLENGES, AND PITFALLS

- Benefits of Automation
  - Improved efficiency in case processing and signal detection.
  - Enhanced accuracy and consistency in data management.
  - Scalability to handle large volumes of safety data effectively.
  - Facilitation of real-time monitoring and faster response to safety issues.
  - Integration with other systems for seamless data exchange and analysis.
- The Challenges of Technology Adoption
  - Resistance to change among staff members accustomed to manual processes.
  - Initial investment costs for acquiring and implementing new technology.
  - Complexity in system integration and compatibility with existing infrastructure.
  - Potential disruptions to workflow during the transition period.
  - Need for continuous training and support to ensure effective utilization.
- The Pitfalls to Avoid
  - Over-reliance on automation leading to complacency or neglect of manual oversight.
  - Risk of data quality issues due to technical errors or algorithmic biases.
  - Regulatory compliance concerns regarding the validation and auditability of automated processes.
  - Cybersecurity vulnerabilities and data privacy risks associated with digital platforms.
  - Failure to address user feedback and adapt technology to evolving needs and challenges.

Roundtable Moderator:
Karthik Muthusamy, *Sr Director, Head of Expedited Safety Reporting,* **Bristol Myers Squibb**

4:30PM THAT´S A WRAP

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. 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. 9 - 10 December, SAN DIEGO
   American Drug Safety Summit 2025 - Westcoast

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: 7 March, 2025
for the latest programe update, please download agenda on conference website

SPEAKING:

Lubos Kusy

lubos@whysummits.com

ATTENDING AND SPONSORING:

Srihari Kamban

shk@whysummits.com

ATTENDING AND SPONSORING:

Rakesh Multani

rakesh@whysummits.com

REGISTER HERE

FROM

$2349

DISCLAIMER

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.