





Updated: 11 May, 2026  
for the latest programme update,  
please download agenda on  
conference website

 14–15 May, 2026

 **London, UK**  
Hilton London Olympia,  
380 Kensington High St,  
London W14 8NL

# 11<sup>TH</sup> PHARMACOVIGILANCE & RWE CONFERENCE 2026

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Silver Partner:



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# INTRODUCTION



Welcome to the 11th Pharmacovigilance & RWE Forum, a culminating conference of our World tour of Pharmacovigilance in heart of European pharma industry, London! After our last annual event we are thrilled to gather our vibrant community of safety professionals to explore the future of pharmacovigilance. Our event features inspiring keynotes, practical case studies, and engaging panel discussions, offering insights from passionate industry experts. Join our numerous networking opportunities to build crucial business relationships and keep up to date with industry developments. Let's come together in London to advance our mission of delivering safer, faster, and more sustainable medicines to patients.

## **OUR MOST PRESTIGIOUS EUROPEAN EVENT, HERE'S WHAT YOU CAN EXPECT:**

**CONNECT & COLLABORATE:** Network with global PV, RWE, and regulatory leaders shaping the future.

**INSIGHTS FROM THE TOP:** Learn from industry visionaries, regulators, and AI innovators driving change.

**HANDS-ON LEARNING:** Dive into interactive keynotes, workshops, and case studies that spark practical takeaways.

**AI & DIGITAL FRONTIERS:** Explore automation, predictive analytics, and next-gen PV strategies in action.

**FUTURE-READY THINKING:** Build 2030-ready PV models, outsourcing strategies, and risk management frameworks.

## **KEY TAKEAWAYS:**

- Decode evolving EMA/MHRA/FDA expectations for AI-enabled PV.
- Apply AI/ML for predictive signals and automated case processing.
- Modernize PSMFs and strengthen digital audit readiness.
- Integrate RWE with clinical data for stronger safety decisions.
- Enhance benefit-risk evaluation with advanced quantitative models.
- Adapt to AI auditing, E2B automation, and digital inspections.
- Design scalable, future-ready PV operating and outsourcing models.
- Transform safety communication using digital and behavioral tools.
- Prepare for 2030 threats- AI bias, cybersecurity, and data fragmentation.

## **YOU WILL SPEND YOUR TIME WITH:**

- Drug safety & Pharmacovigilance executives
- Heads of global safety programs
- QPPVs
- Benefit-Risk assessment management
- Medical affairs management
- RWE specialists
- Patient safety management
- Compliance specialists
- Post-market researchers
- PV auditors
- Regulatory affairs directors
- EMA professionals
- Compliance specialists
- Pharma IT management
- Safety consultants

# TESTIMONIALS



**Karen Forsha Ph.D.**  
L&D Change Management and  
Training Leader  
Terumo Medical Corp.  
★★★★★

„I had the opportunity to offer participants insight on how to positively impact others' well-being and influence organizational outcomes by viewing resilience, grit, and growth mindset as their leadership superpower! The dialogue afterwards was inspiring.“



**Gunther Lenz**  
Vice President Software R&D  
Biosciences BD  
★★★★★

„Digital Transformation in PPM at the #MedTechSummit! It's always inspiring to connect with fellow professionals who are equally passionate about harnessing digital tools to revolutionize project and portfolio management in healthcare. Let's continue this conversation and keep the ideas flowing!“



**Susanna Girard, MBA, PMP, ACP**  
Senior R&D Program Manager  
J&J MedTech  
★★★★★

„Great discussions! It was my pleasure to be a part of it and get to know so many great people working in the industry.“



**Sarah Paro**  
Global QMS Associate  
Director  
★★★★★

„Last week I had the opportunity to share my experiences and learn from industry experts at Why Summits MedTech Summit. It was an incredible experience!“



**Arite Wildau**  
Director Patient Safety  
BIOTRONIK  
★★★★★

„Great open dialogue in an expert community. Many valuable presentations, panel discussions and time for networking to share best practices and different views on similar challenges. Warm atmosphere to grow as team over two fabulous days. Also excellently organized and moderated by the WHY SUMMIT TEAM. Happy to join next year as well!“



**Benjamin Rochette**  
Vice President, Global Regulatory  
Affairs  
Coloplast  
★★★★★

„I joined the conference in Spring 2023 and really enjoyed it. The program covered several topics of direct relevance to my daily activities, while also giving me perspectives on 'macro trends' of the medical devices industry. Speakers were experts and participants motivated to interact between sessions.“



**Surinder Dhillon**  
Head of Commercial PMO,  
International  
Hologic  
★★★★★

„I found the sessions were well organized, with an interesting mix of attendees from across the industry. Various key topics were covered, all pertinent to the current MedTech landscape with good discussions on common challenges and sharing of useful lessons, practical applications and future proofing strategies.“



**Renea Olsen**  
Post-Market Surveillance  
Manager, Scientific Affairs  
3shape  
★★★★★

„The fact that the conference is relatively small generates a very open dialog and it makes it easy to network“

# 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

# CURRENT SPEAKERS



**Jenn Matthissen**

Head of Gastrointestinal system, nutrition, endocrine and fertility

**Medicines and Healthcare products Regulatory Agency**



**Ashish Dwivedi**

Chief Customer Officer  
**Synamed**



**Jean Redmond**

Chief Operating Officer  
**Biologit**



**Sahil Sahni**

Director of Safety Systems  
**Mundipharma**



**Dr. Jay Dave**

Technical Director Global PV & Risk Management  
**COD Research**



**Mohammed Mohammed**

Senior PV Quality Systems Associate  
**Amicus Therapeutics**



**Dr. Joan Dsouza**

CEO  
**JD Pharma Services**



**Arijit Patra**

Senior Principal Scientist  
**UCB**



**Karin Kempe**

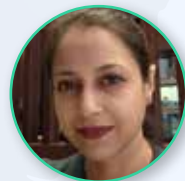
EU QPPV  
**Karo Pharma**



*In the Chair*

**Gurpreet Singh**

Lifesciences & Pharma Business Leader



**Punam Kumari**

Founder and Managing Director  
**Biovance Solutions**



**Susan Hodgson**

Head of Observational Research, CPRD  
**MHRA**



**Chetan Shatapathy**

Executive Director, Patient Safety Oncology and Head ADC Patient Safety  
**AstraZeneca**

# CURRENT SPEAKERS



**Mark Widdowson**  
Senior Innovation Manager  
**Bristol Myers Squibb**



**Begum Benli Peker**  
Director, Head of Patient Safety NL & EU Hub  
**Bristol Myers Squibb**



**Dammika Peiris**  
Director, Pharmacovigilance  
**Takeda**



**Sumit Munjal**  
Global Head of Medical Safety  
**Otsuka Pharmaceutical**



**Swasti Gurung**  
Director, PV Quality  
**Amicus Therapeutics**



**Raj Bhogal**  
Sr. Director, R&D Business  
Strategy & Operations  
**Jazz Pharma**



**Shikta Das**  
Scientific Lead Real World  
Evidence  
**Astrazeneca**



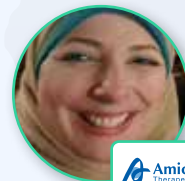
**Sanjeev Srivastav**  
Signal Management Lead  
**BioNTech UK Limited**



**Elena Carmen Radu**  
Senior Global Drug Safety  
Physician  
**Basilea**



**M Ali Memon**  
Chief Medical Officer  
**Complement Therapeutics**



**Zina Sadeq**  
Director, Regional PV  
and Alliance Management,  
UK QPPV  
**Amicus Therapeutics**



**Abdul Rahim**  
Founder & Director  
**Alwis Solutions**

# CONFERENCE AGENDA

# DAY 0

## 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.

## EVENING BEFORE SUMMIT:



# DAY 1

## 8:30 REGISTRATION & EARLY NETWORKING COFFEE

## 9:00 CHAIRPERSON OPENING REMARKS

## 9:10 START WITH A WHY? ROUNDTABLE DISCUSSION

### Meet Your Peers, Share Your Priorities, and Set Your Objectives

A short, structured icebreaker designed to help delegates connect early, promote networking, share challenges and priorities, and start the conference with more relevant conversations.

## 9:30

### Keynote: The Evolving EU & UK Regulatory Landscape – Strategic Implications for PV & RWE in 2026

- Integrating MHRA & EMA's latest guidance into global safety frameworks
- Anticipated regulatory direction for AI-enabled PV decision-making
- Optimizing lifecycle risk management in a dynamic regulatory environment

**Jenn, Matthissen**, Head of Gastrointestinal system, nutrition, endocrine and fertility, The Medicines and Healthcare products Regulatory Agency, UK

## 10:00

### Case Study: Building Regulatory-Ready AI in Pharmacovigilance – Lessons from Global Implementations

This case study shares practical lessons from global AI-enabled pharmacovigilance implementations, focusing on regulatory readiness, governance, and inspection defensibility under evolving EMA and MHRA expectations.

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

## 10:30

### Panel Discussion: Advancing the Future of Pharmacovigilance

- What principal challenges warrant our strategic attention?
- Key emerging trends and technological developments influencing the discipline
- how to anticipate, prioritize, and mitigate safety risks across global markets

#### Moderator:

**Gurpreet Singh**, Lifesciences & Pharma Business Leader

#### Speakers:

**Punam Kumari**, Founder and Managing Director, Biovance Solutions

**Sanjeev Srivastav**, Signal Management Lead, BioNTech UK Limited

**Chetan Shatapathy**, Executive Director, Patient Safety Oncology and Head ADC Patient Safety, AstraZeneca

**Dammika Peiris**, Former Head of PV, UK & Ireland, Takeda

## 11:00 MORNING COFFEE & NETWORKING BREAK

## 11:30

### Keynote: Pharmacovigilance in a Digital Era – Ensuring Inspection Readiness, Compliance & Regulatory Confidence

- Leveraging AI and digital tools for inspection-ready PV systems
- Maintaining compliance and data integrity in automated workflows
- Enhancing regulatory confidence through predictive safety intelligence

**Raj Bhogal**, Sr. Director, R&D Business Strategy & Operations, Jazz Pharma

12:00

**Case Study: Real-world use cases of AI and automation in Pharmacovigilance operations – exploring how to drive efficiency gains without compromising compliance in literature monitoring**

**Jeann Redmond**, Chief Operating Officer, Biologit

12:30

**Panel Discussion: AI-Driven Signal Detection & Causality Assessment – From Algorithms to Regulatory Confidence**

- How AI-driven causality frameworks are reshaping signal detection strategies
- Balancing automation with expert medical judgment
- Regulatory expectations for transparency, validation, and explainability
- Managing false positives, bias, and model drift
- Practical lessons from real-world implementations

**Moderator:**

**Sanjeev Srivastav**, Signal Management Lead, BioNTech UK Limited

**Speakers:**

**Chetan Shatapathy**, Executive Director, Patient Safety Oncology and Head ADC Patient Safety, AstraZeneca

**Mohammed Mohammed**, Senior PV Quality Systems Associate, Amicus Therapeutics  
**Jenn Matthissen**, Head of Gastrointestinal system, nutrition, endocrine and fertility, The Medicines and Healthcare products Regulatory Agency, UK

13:00 LUNCH BREAK

14:00

**Panel Discussion: Harnessing Real-World Evidence to Revolutionize Pharmacovigilance and Regulatory Decision-Making**

Industry experts come together to share real-life experiences on using real-world evidence to strengthen pharmacovigilance and regulatory decisions. The discussion focuses on practical ways to connect RWE with clinical data and turn insights into better safety outcomes for patients and regulators.

**Moderator:**

**Shikta Das**, Scientific Lead Real World Evidence, AstraZeneca

**Speakers:**

**Zina Sadeq**, Director, Regional PV and Alliance Management, UK QPPV, Amicus Therapeutics

**M Ali Memon**, Chief Medical Officer, Complement Therapeutics  
**Karin Kempe**, EU QPPV, Karo Pharma

14:30

**Fireside Chat: COLLABORATIVE DIGITAL DATA ENVIRONMENTS FOR ENHANCING RISK COMMUNICATION TO PATIENTS**

This session highlights how collaborative digital data environments can improve the way safety risks are communicated to patients. Real-world examples show how connected data and digital tools help deliver clearer, timelier and more patient-focused risk information.

**Moderator:**

**Dr. Joan Dsouza**, CEO, JD Pharma Services

**Speaker:**

**Begum Benli Peker**, Director, Head of Patient Safety NL & EU Hub, Bristol Myers Squibb

15:00

**Reserved Presentation: Where Deep PV Science Meets Real AI Engineering: A New Standard for Signal Intelligence.**

**Live demo on real regulatory data**

- What "AI-native pharmacovigilance" should actually mean.
- A concrete model for how PV, Quality, and IT functions can co-own a signal intelligence operation that's regulator-grade by construction
- Continuous signal detection as the new scientific standard

**Ashish Dwivedi**, Chief Customer Officer, Synamed

15:30 AFTERNOON COFFEE BREAK

16:00 ROUNDTABLE DISCUSSIONS

**Roundtable 1: Future Threats & Future Solutions – Designing the PV Operating Model for 2030**

- Key disruption drivers and emerging threats
- Co-creating next-generation PV operating models
- 2030 readiness priorities and strategic next steps

**Karin Kempe**, EU QPPV, Karo Pharma

**Roundtable 2: Real-World Evidence at Scale – From Data Integration to Regulatory Impact**

- Aligning RWE generation with evolving EMA, MHRA, and FDA expectations
- Overcoming data fragmentation across clinical, post-marketing, and digital sources
- Ensuring data quality, traceability, and methodological robustness
- Translating RWE insights into actionable regulatory and safety decisions
- Lessons learned from successful RWE-driven submissions and label updates

**Zina Sadeq**, Director, Regional PV and Alliance Management, UK QPPV, Amicus Therapeutics

# CONFERENCE **AGENDA**



# DAY 1

## **Roundtable 3: Regulatory Digitalisation & Global PV Readiness – What Compliance Will Look Like in 2030**

- Digitised submissions & AI-reviewed safety files
- Multi-region compliance with lean teams
- Automation in inspection readiness
- Future regulatory reporting frameworks

**Shikta Das**, *Scientific Lead Real World Evidence*, **Astrazeneca**

**17:00 CLOSING REMARKS – END OF DAY 1**

## 8:50 OPENING REMARKS FROM CHAIRPERSON

9:00

### **Keynote: From Data to Safer Patients: Using CPRD Real-World Data to Strengthen Pharmacovigilance and Regulatory Decisions**

- Leveraging CPRD real-world data to enhance signal detection and proactive risk monitoring in routine clinical practice
- Applying robust epidemiological methods to generate regulatory-grade evidence that supports MHRA and EMA decision-making
- Translating real-world insights into actionable safety strategies that improve patient protection and benefit-risk assessment

**Susan Hodgson**, *Head of Observational Research, CPRD, The Medicines and Healthcare products Regulatory Agency, UK*

9:30

### **Patient-Centric Safety Strategies: Incorporating Patient Prospectives in PV**

- Focus on integrating patient perspectives into PV Processes
- Strategies to involve patients and improve drug safety outcomes

**Begum Benli Peker**, *Director, Head of Patient Safety NL & EU Hub, Bristol Myers Squibb*

10:00

### **Panel Discussion: Improving Cross-Collaboration Between Local & Global PV**

- Bridging local-global gaps in decision-making across case processing, signal detection, and risk management while respecting regulatory nuances
- Strengthening collaboration with regulators through proactive, transparent communication and consistent safety messaging
- Enhancing QPPV oversight with real-time visibility, control, and accountability across global and local systems

#### **Moderator:**

**Raj Bhogal**, *SSr. Director, R&D Business Strategy & Operations, Jazz Pharma*

#### **Speakers:**

**Sumit Munjal**, *Global Head of Medical Safety, Otsuka Pharmaceutical*

**Elena Carmen Radu**, *Senior Global Drug Safety Physician, Basilea*

**Susan Hodgson**, *Head of Observational Research, CPRD, The Medicines and Healthcare products Regulatory Agency, UK*

**Swasti Gurung**, *Director, PV Quality, Amicus Therapeutics*

10:30 NETWORKING COFFEE BREAK

11:00

### **Safety System Gap Analysis for Combination Products: A tool to assure MHRA inspection Readiness**

**Dr. Jay Dave**, *Technical Director Global PV & Risk Management, COD Research*

11:30

### **Insight Talk: Leveraging Post-Marketing Registries for RWE and Regulatory Impact**

Understand how post-marketing registries generate robust real-world evidence to support regulatory decisions and lifecycle management. Gain practical insights on optimizing data use, maintaining compliance, and turning registry findings into impactful safety and effectiveness outcomes.

**Zina Sadeq**, *Director, Regional PV and Alliance Management, UK QPPV, Amicus Therapeutics*

12:00

### **Keynote: Building Inspection-Ready Safety Systems: Ensuring Compliance, Scalability & Global Integration in Pharmacovigilance**

- Building inspection-ready PV systems with built-in compliance and audit trails
- Ensuring scalable and globally consistent safety operations across regions
- Integrating technology and governance for end-to-end traceability and compliance

**Sahil Sahni**, *Director of Safety Systems, Mundipharma*

12:30 LUNCH BREAK

13:30

### **Panel Discussion: Advanced Benefit-Risk Assessment – Quantitative Approaches, AI Modelling & RWE Integration**

- Quantitative methodologies
- AI-enabled modelling
- Integration of real-world insights

#### **Moderator:**

**Dr. Joan Dsouza**, *CEO, JD Pharma Services*

#### **Speakers:**

**Elena Carmen Radu**, *Senior Global Drug Safety Physician, Basilea*

**Arijit Patra**, *Senior Principal Scientist, UCB*

**Chetan Shatapathy**, *Executive Director, Patient Safety Oncology and Head ADC Patient Safety, AstraZeneca*

## 14:00 ROUNDTABLE DISCUSSIONS

### Roundtable 1: Modern Risk Management Excellence – Integrating AI with Evolving Regulatory Expectations

- AI's influence on RMP development
- Maintaining compliance during automation
- Lessons from recent audits
- Harmonizing global risk minimisation strategies

**Raj Bhogal**, Sr. Director, R&D Business Strategy & Operations, **Jazz Pharma**

**Dammika Peiris**, Former Head of PV, UK & Ireland, **Takeda**

### Roundtable 2: Future Strategy Forum – What Will Define Global Pharmacovigilance in the Next Decade?

- Digital-first safety teams
- Real-time RWE ecosystems
- Opportunities & blind spots for 2026–2030

**Chetan Shatapathy**, Executive Director, Patient Safety Oncology and Head ADC Patient Safety, **AstraZeneca**

### Roundtable 3: AI Governance, Accountability & Ethics in Pharmacovigilance

- Defining accountability in AI-supported safety decision-making
- Managing bias, model drift, and data quality risks
- Aligning AI governance frameworks with evolving EMA, MHRA, and FDA expectations
- Establishing ethical, transparent, and auditable AI oversight models

**Sumit Munjal**, Global Head of Medical Safety, **Otsuka Pharmaceutical**

## 15:00 NETWORKING BREAK

## 15:30

### Round-Table Insight Exchange: Future Priorities: What Leaders Need to Focus on Next

- Discuss key upcoming priorities shaping safety systems, evidence generation, and operational readiness
- Align on practical next steps to address emerging challenges and strengthen decision-making across organisations

**Gurpreet Singh**, Lifesciences & Pharma Business Leader

## 16:00 CONFERENCE CLOSURE

# 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: 11 May, 2026  
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download agenda on conference website



## Speaking:

## Attending and Sponsoring:



**Nidhi Singhal**  
nidhi.singhal@whysummits.com



**Lubos Kusy**  
lubos@whysummits.com



**Rakesh Multani**  
rakesh@whysummits.com

### 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.

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### REGISTRATION



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