

# Meet the first onboarded speakers

## to 2025 edition:



BIONTECH

**Sanjeev Srivastav**  
Signal Management Lead  
BionTech



sobi  
sore strength

**Michael von Forstner**  
Head of Safety Science  
SOBI



NOVARTIS

**Petros Mavrogenis**  
Head Vigilance Process Excellence  
Novartis



NOVARTIS

**Luvanka Hanxhari**  
Senior Manager Agregate Reports  
& Risk Management – RMP  
Novartis



Roche

**Adriano Galati**  
Digital Safety Director  
Pharmacovigilance & Scientific  
Development  
Roche



SANDOZ

**Marija Simic  
Koumoutsaris**  
Director Medical Safety  
Sandoz



Roche

**Jost Leemhuis**  
Patient Safety Partner  
Roche



basilea

**Elena Radu**  
Senior Drug Safety Physician  
Basilea Pharmaceutica  
International Ltd.



bionika

**Marjan Dzeparoski**  
PV Manager & University lecturer  
Bionika Pharmaceuticals/UGD



ORGANON

**Mircea Ciuca**  
Global Head Medical Safety  
Organon



Baxter

**Monika Zych**  
PS Director, CEEI&META, UKI &  
Nordics, DACH  
Baxter



sanofi

**Remco M. Diab**  
Sr. Dir. Lead Global Safety Officer  
Immunology & Inflammation  
Sanofi



Debiopharm

**Etienne Raemy**  
Head of Pharmacovigilance  
Debiopharm Research &  
Manufacturing



ALWIS

**Abdul Rahim**  
Founder & Director  
Alwis Group



biologit

**Jean Redmond**  
COO  
Biologit



Bristol Myers  
Squibb

**Sabine Poltermann**  
Head of Country Patient Safety  
Switzerland  
BMS



MOLECULAR  
PARTNERS

**Marianne Soergel-Ahovi**  
Head Drug Safety  
Molecular Partners



ZEYTUN  
PHARMACEUTICALS

**Nurana Aghayeva**  
Head of Quality and  
Pharmacovigilance Department  
Zeytun Pharmaceuticals LLC

# Day2

8:30	MORNING REGISTRATION AND EARLY BIRDS NETWORKING COFFEE
9:00	OFFICIAL START OF WORLD DRUG SAFETY SUMMIT WITH OPENING REMARKS FROM WHY SUMMITS AND THEIR CHAIRPERSON
9:10	<b>ROUND-TABLE DISCUSSION: DIGITALIZATION OF PV</b> <ul style="list-style-type: none"><li>Where can we see the biggest impact of digital solutions in PV?</li><li>Practical applications of AI</li><li>Are we digitally ready? The real state of PV digital maturity in 2025</li></ul>
9:40	<b>LEGAL REQUIREMENTS FOR PSSF AND COMPARISON TO PSMF</b> <ul style="list-style-type: none"><li>PSMF vs PSSF</li><li>Creating local PV system description</li><li>Adjusting PSSF to local business models</li></ul> <b>Monika Zych</b> , PS Director, CEEI&META, UKI & Nordics, DACH, <b>Baxter</b>
10:10	<b>CASE STUDY: RESERVED FOR ALWIS GROUP</b> <b>Abdul Rahim</b> , Founder & Director, <b>Alwis Group</b>
10:40	COFFEE BREAK & NETWORKING
11:10	<b>SIGNAL MANAGEMENT: LET'S GET REAL!</b> <ul style="list-style-type: none"><li><b>Signal Management is Core to Pharmacovigilance:</b> It plays a central role in identifying, assessing, and acting on safety signals to protect patients effectively.</li><li><b>Embrace of New Technologies:</b> The integration of AI, big data analytics, wearables, and predictive modeling can dramatically enhance the speed and accuracy of signal detection.</li><li><b>Real-time Monitoring is the Future:</b> Continuous, real-time data from clinical trials, post-marketing surveillance, and wearables can revolutionize safety monitoring.</li><li><b>Need for Regulatory Harmonization and Standardization:</b> Variability across regulators, academia, and industry calls for unified methods and global standards like READUS-PV.</li><li><b>Call for a PV Mindset Shift:</b> The presentation urges a redefinition of pharmacovigilance practices—moving from reactive to proactive, integrated, and tech-enabled signal and risk management.</li></ul> <b>Mircea Ciuca</b> , Global Head Medical Safety, <b>Organon</b>
11:40	<b>RISK COMMUNICATION</b> <ul style="list-style-type: none"><li>Ensuring steps in ensuring relevant, clear, accurate and consistent</li><li>Emphasis on DHPC</li><li>How we do so in the Balkan region</li></ul> <b>Marjan Dzeperoski</b> , PV Manager & University Lecturer, <b>Bionika Pharmaceuticals/UGD</b>
12:10	<b>PANEL DISCUSSION: PV RISK MANAGEMENT</b> <ul style="list-style-type: none"><li>Interactions between medical affairs and pharmacovigilance to enhance effectiveness of the risk management strategy</li><li>Enhancing data effectiveness and risk management</li></ul>

	<ul style="list-style-type: none"><li>Regulatory compliance &amp; risk management</li></ul> <b>Luvanka Hanxhari</b> , Senior Manager Aggregate Reports & Risk Management – RMP, <b>Novartis</b> <b>Mircea Ciuca</b> , Global Head Medical Safety, <b>Organon</b> <b>Marjan Dzeperoski</b> , RA & PhV Manager, <b>Bionika Pharmaceuticals/UGD</b> <b>Nurana Aghayeva</b> , Head of Quality and Pharmacovigilance Department, <b>Zeytun Pharmaceuticals LLC</b> <b>Marianne Soergel</b> , Head Drug Safety, <b>Molecular Partners</b>
12:40	LUNCH BREAK
13:40	<b>HOW MUCH CAN AI CONTROL DRUG SAFETY DOCUMENTATION?</b> <ul style="list-style-type: none"><li>The capabilities and limits of AI in creating highly regulated documents</li><li>The more significant issue of complex data integration</li><li>Automation and on-demand document generation are the real goals</li></ul> <b>Emerson Welch</b> , VP Global Marketing, <b>Quark</b>
14:10	<b>PANEL DISCUSSION: AI IN PHARMACOVIGILANCE: HYPE VS. REALITY IN SAFETY INTELLIGENCE AND DECISION-MAKING</b> <ul style="list-style-type: none"><li>Where Are We Actually Seeing Value?</li><li>Regulatory &amp; Ethical Alignment: Navigating EMA expectations, ensuring explainability, and addressing data privacy and bias in AI tools.</li><li>Operational Integration: Real-world use cases of AI in ICSR processing, signal detection, and literature monitoring—what's working and what's not.</li></ul> <b>Panelists:</b> <b>Mircea Ciuca</b> , Global Head Medical Safety, <b>Organon</b> <b>Michael Forstner</b> , Head of Safety Science, <b>SOBI</b> <b>Jean Redmond</b> , COO, <b>Biologit</b> <b>Emerson Welch</b> , VP Global Marketing, <b>Quark</b>
14:50	<b>ADVANCEMENTS IN VACCINE SAFETY: LANDSCAPE FOR PERSONALISED VACCINE</b> <ul style="list-style-type: none"><li>Evaluating the current state of patient and safety-centric practices in major pharmaceutical companies.</li><li>Identifying opportunities for enhancing patient engagement and safety protocols in rapidly advancing landscape of personalized vaccines.</li></ul> <b>Sanjeev Srivastav</b> , Signal Management Lead, <b>BioNTech</b>
15:20	COFFEE & NETWORKING BREAK
15:50	<b>ROUND-TABLE DISCUSSION: SETTING VISIONS FOR 2026</b> <ul style="list-style-type: none"><li>Workforce skills gap: preparing PV professionals for tomorrow</li><li>How can PV keep up with complex products whose safety profiles are less predictable and more individualized?</li><li>Predictions for 2026</li><li>Lessons from 2025</li></ul>
16:20	CLOSING REMARKS FROM CHAIRPERSON AND WHY SUMMITS