

WORLD
PATIENT SAFETY
CONGRESS EUROPE

22-24 September, Amsterdam – RAI Hall 3

TBC = Speakers who have confirmed but yet to determine their session

1. **TBC Patrick Caubel**, Chief Safety Officer, **Pfizer**
2. **Mariette Boerstoeel Streefland**, Senior Vice President, Worldwide Patient Safety Officer, **Bristol Myers Squibb**
3. **Stewart Geary**, Global Safety Officer, **Eisai**
4. **Jijo James**, Chief Medical Officer, MedTech & Interventional Oncology, **Johnson & Johnson**
5. **Jens-Ulrich Stegmann**, Senior Vice President, Head, Clinical Safety and Pharmacovigilance, EU QPPV, **GSK**
6. **Serban Ghiorghiu**, Deputy Chief Medical Officer, Chief Safety Officer, **AstraZeneca**
7. **Tjark Reblin**, Senior Vice President, Global Head of Patient Safety, **Ipsen**
8. **Fabian Heisig**, Senior Vice President, Chief Medical Officer, Head Global Drug Safety & QPPV, **Grunenthal**
9. **Sarah Vaughan**, Head of Vigilance Operations, **MHRA**
10. **Phil Tregunno**, Deputy Director, Patient Safety Monitoring, **MHRA**
11. **TBC Uwe Gudat**, Chief Medical Officer, **Biocon Biologics**
12. **Rania Mouchantaf**, Executive Director, **Health Canada**
13. **Vicki Edwards**, Vice President, Pharmacovigilance Excellence & International QPPV, **AbbVie**
14. **Claudia Lehmann**, Vice President, Head, Patient Safety & Pharmacovigilance Operations, **Boehringer Ingelheim**
15. **Magnus Nord**, Vice President, Global Patient Safety, Biopharma, **AstraZeneca**
16. **Lalitha Mahadavan**, Vice President, Clinical Research and Patient Drug Safety, **Amicus Therapeutics**
17. **Jorge Carmona**, Global Product Line Lead (Head), Patient Safety Risk Management, **Roche**
18. **Juan Daccach**, Vice President, Global Product Safety, **Merz Aesthetics**
19. **Michelle Motta Dardeno**, Vice President, Head of Global Patient Safety, **Aurinia**
20. **Attila Olah**, Vice President, Head, Global Patient Safety, EU-QPPV, **Gedeon Richter**
21. **TBC Sven Kohler**, Vice President, EU-QPPV and Head Regional Patient Safety and PV, **Boehringer Ingelheim**
22. **Howard Snow**, Vice President, Global Head of Pharmacovigilance, **Sobi**
23. **Klaudija Marijanovic Barac**, Associate Vice President, EU QPPV, **Eli Lilly**
24. **Simon Ashworth**, Global Head of Safety, **Menarini**
25. **Mohammed Ali Kotal**, EU-QPPV & Head QPPV Office, **Sandoz**
26. **Annette Humes**, Chief of Staff, Global Head of Safety Resources and Alliance Management, **Roche**
27. **Nicola Charpentier**, Vice President, Head of Pharmacovigilance, **BioNTech SE**
28. **Willemijn van der Spuij**, Executive Director Europe, Patient Safety International, **Bristol Myers Squibb**
29. **TBC Ona Kinduryte Schorling**, Vice President, Global Medical Safety, **Lundbeck**
30. **Emma Outram**, Group Head, Safety Data Acquisition, **Roche**
31. **Fabio De Gregorio**, Vice President Global Patient Safety, TA Rare Diseases Head, **Ipsen**
32. **Gloria Bustos**, Global Head, Patient Safety, **Vantive**
33. **Alex Bica**, Global Head of Early Development Safety, **CSL**
34. **Sean Burke**, Executive Director, Regional Lead, International Pharmacovigilance, **MSD**
35. **Karen van der Velden**, Head, Global Pharmacovigilance Operations, **Boehringer Ingelheim Vetmedica**
36. **Thomas Kuckuk**, Head, Pharmacovigilance Systems Management, Patient Safety & Pharmacovigilance, **Novartis**
37. **Catherine Tchinou**, Head of Medical Safety, Biopharma, **Sandoz**
38. **Elena Prokofyeva**, Head of Drug Safety Unit, Department of R&D, **Federal Agency for Medicines and Health Products, Belgium**
39. **Minhaj Obeidullah**, Global Head, Governance and Risk, **Novartis**
40. **TBC Lisa Benaise**, Head of Global Pharmacovigilance, **Miltenyi Biotech**
41. **TBC Rafael Josupeit**, EEA-UK QPPV, **Procter & Gamble**
42. **Dany Ward**, Executive Director, Head of PV Ops & Global Risk Management, **Jazz Pharmaceuticals**
43. **Baseer Ahmed**, Executive Director, Drug Safety and Pharmacovigilance, **Ionis Pharma**
44. **Heinz Weidenthaler**, Senior Director, Safety Strategy Lead, Oncology, **BioNTech SE**
45. **Roger Mutter**, Medical Safety Director, **Alfasigma**
46. **Lily Yonghui Sun**, Medical Director, **Idorsia Pharmaceuticals**
47. **Blanca Berrocal Gonzalez**, Head of Pharmacovigilance Compliance and International Engagement, **Veterinary Medicines Directorate**
48. **Michael von Forstner**, Chief Scientific Officer, **MedGenie**
49. **Jolanda De Bruijne**, Senior Director, Head of PV Compliance, **Teva Pharmaceuticals**
50. **Julia Appelskog**, Head of QPPV Office, **CSL**
51. **Wivina De Waele**, Senior Director, Safety Lead Europe, Global Patient Safety, **AstraZeneca**
52. **Paraskevi Floroskoufi**, Regional PV Head, Europe and Eurasia, **Opella**
53. **Yasmina Bouaziz**, Signal & Risk Management Lead, **Opella**
54. **Pedro Gomes**, Global Director, Pharmacovigilance Quality Assurance Lead, **MSD**
55. **Jamal Baig**, Director, Drug Safety, **MSD**
56. **Sanjeev Srivastav**, Signal Management Lead, **BioNTech**
57. **Gillian Diesel**, Director of Pharmacovigilance REMEA, **Elanco Animal Health**
58. **Elena Keller**, Director, PV, RA, Quality and Medical Operations, Local QPPV, **Ipsen DACH**
59. **Ariane Stollenwerk**, Director, Head of Safety Central Europe & APAC, **UCB**
60. **Petar Gjorgiev**, Global Patient Safety Program Lead, **Regeneron**
61. **Zina Sadeq**, Director, Regional PV and Alliance Management, UK QPPV, **Amicus Therapeutics**
62. **Ranjana Khanna**, Global Director, GVP, QA, R&D Quality, **BeOne Medicines**
63. **Valentina Mancini**, Senior Director, Pharmacovigilance, EU & UK QPPV, **Shionogi**
64. **Laura Paolo Boga**, Senior Director, Head of Global Pharmacovigilance, UK & EU QPPV, **Dompe**
65. **Linda Harmark**, Director, **Drug Safety Research Unit**
66. **Amir Lahouegue**, Director, Patient Safety & Cluster Lead, France & Benelux, **AstraZeneca**
67. **György Zörényi**, Senior Medical Director, Medical Safety, **Jazz Pharmaceuticals**
68. **Luis Guedes**, Global Product Safety Science Lead, **Sobi**
69. **Israel Gutierrez**, Chief Medical Officer, **TLR Therapeutics**
70. **Suzanne Foncin**, Senior Scientific Director and Group Leader, Safety Evaluation and Risk Management, **GSK**
71. **Giovanni Furlan**, Head, Medical Safety Operations, **Sandoz Germany**
72. **Delphine Bertram**, Senior Director, Global Pharmacovigilance, QPPV, **Pharming**
73. **Mijal Chavda**, Senior Director, Global Head, GxP Inspections & GVP Quality, **Kyowa Kirin**
74. **Mohamed Abdillahi**, Senior Director, Risk Management, **AstraZeneca**
75. **TBC Franziska Rathjens**, Head of Business Process Management & PV Tools, Deputy QPPV, **B.Braun**
76. **Nadine O’Hare**, Senior Director, Global Patient Safety, PV Intelligence, **Regeneron**
77. **Andrea van Poppel-Rosier**, Associate Director, Global Patient Safety, QPPV Operations, GPS, **Regeneron**
78. **Ricarda Berg**, Head of Drug Safety & Local QPPV, Germany, **GSK**
79. **TBC Daria Rasa**, Head of Corporate Pharmacovigilance, EU QPPV, **Alfasigma**
80. **Andrea Oliva**, Head of Pharmacovigilance, Italy, **Viatis**
81. **Yvonne Schäfer**, Head of Patient Safety and Pharmacovigilance Systems Business Solutions, **Boehringer Ingelheim**
82. **Fabio Miceli**, Director EU/UK QPPV, **Norgine**
83. **Delphine Saragoussi**, Head of Pharmacoepidemiology, Vaccines, Patient Safety & Pharmacovigilance, **Sanofi**
84. **Marie-Laure Kurzinger**, Head of Pharmacoepidemiology, General Medicine, **Sanofi**
85. **TBC Jan Cleerbout**, Deputy EU QPPV, **Johnson & Johnson Innovative Medicine**
86. **Sutirtha Mukhopadhyay**, Senior Associate Director, Patient Safety Physician, **Boehringer Ingelheim**
87. **Teodora Perger**, Visiting Lecturer, Centre for Pharmaceutical Medicine Research, **King’s College London**
88. **Ilaria Grisoni**, Executive Director, Head of EU & International Pharmacovigilance, QPPV Office and EEA QPPV, **Jazz Pharmaceuticals**
89. **TBC Marcin Marciniak**, Senior Director, Global Safety and PV Expert WHC, **Gedeon Richter**
90. **Peter Kohut**, Senior Director, Head of Pharmacovigilance, **Alvotech**
91. **Binh To**, Patient Safety Europe Lead & Local QPPV, **BeOne Medicines**
92. **Zoe Hamill**, Senior Director, Global Development Quality Management, **Regeneron**
93. **Sylvain Nicolas**, Global Head, Safety Data Strategy and Data Management, **Sanofi**
94. **TBC Samuel Wallis**, Senior Director, Global Head of ICSR Case Processing, **Bristol Myers Squibb**

95. **Joachim Vandepitte**, Country Patient Safety Head, **Novartis Belgium**
96. **Stefanie Amend-Mall**, Director, Patient Safety Europe, **Sandoz**
97. **Karthick Sukumaran**, Director, Technology Enablement, Intelligent Safety Automation, **Roche**
98. **Judy Barretto**, Senior Director, Virology, TA, Patient Safety, **Gilead**
99. **Mette Stie Kallesøe**, Head of Pharmacovigilance, QPPV, **Hansa Biopharma**
100. **Marjan Dzeparoski**, RA & PV Manager, **Bionika Pharmaceuticals** & Lecturer, Medicine Faculty, **Goce Delčev University of Štip**
101. **Marcin Kruk**, Senior Director, Drug Safety Unit Regional Head, Europe, Africa & Middle East, **Pfizer**
102. **Antonella Fretta**, Senior Director, Aggregate Reporting Team Lead, **Pfizer**
103. **TBC Erica Baval**, Senior Director, Patient Safety & PV, **Corcept Therapeutics**
104. **Akhilesh Chamediya**, Global Medical Director, Patient Safety Lead, **Alexion & AstraZeneca**
105. **Maria Jose Reneses**, Senior Director, Deputy EU QPPV and Head of PSMF Team, **Takeda**
106. **Angela Schmidt-Mertens**, EU QPPV & General Safety Officer, **Eisai EMEA**
107. **Sylvie Bartus**, Senior Director, Clinical Safety Global, Clinical Affairs, Surgical Structural Heart, **Edwards Lifesciences**
108. **Pedro Caetano**, Senior Safety Physician, Oncology, Global Patient Safety, **Debiopharm**
109. **Bogdana Balas**, Group Medical Director, Late-Stage & Marketed Medicines Safety, **Roche**
110. **Francesca Dickins**, Advisor, Medical Quality Organisation, **Eli Lilly**
111. **TBC Tony Simon**, Director, European Scientific Affairs and Pharmacovigilance, **Zoetis**
112. **Aya Zaghloul**, Associate Director, Global Patient Safety, **Eli Lilly**
113. **Ludovic Apoux**, Director, Global Lead, Signal Detection, **Haleon**
114. **Gemma Sayers**, Team Lead Quality Auditing (PV), R&D Quality Assurance, **GSK**
115. **Siva Kumar Buddha**, Medical Director, Global Patient Safety, **Amgen**
116. **Melanie Dullemont**, PV Quality Management System Head, **Sanofi**
117. **Bolatito Abatan**, Director, Global Patient Safety, International Office, **BeOne Medicines**
118. **Johanna Strandell**, Director, Patient Safety, **Camurus AB**
119. **Rohan Mane**, Director of Risk Management, **Regeneron**
120. **Mark Daniels**, Director, Safety Physician, **Jazz Pharmaceuticals**
121. **Magdalena Godula**, Director, Regional Safety Platform Lead, **Pfizer**
122. **TBC Shanti Werther**, Global Safety Head, Immunology, Patient Safety Biopharma, **AstraZeneca**
123. **Amy Ryan**, Director, Patient Safety Inspection Excellence, **AstraZeneca**
124. **Dimitris Zampatis**, Director, Product Patient Safety, **Sandoz**
125. **Magdalena Niedzielko**, Academic Teaching Assistant, Department of Experimental and Clinical Pharmacology, **Medical University of Warsaw**
126. **Darko Krnic**, Director, Head of Medical Information & PV, **Pharma&**
127. **Maritess Esguerra**, Senior PV Process Director, **Genentech**
128. **Pav Rishiraj**, Head of Pharmacovigilance, **Celltrion**
129. **Fee Gedlich**, Lead Patient Safety Physician, Cardiovascular and Established Products, **Boehringer Ingelheim**
130. **Jost Leemhuis**, Senior Patient Safety Partner and Global Business Lead, **Roche**
131. **Begum Benli Peker**, Director, Head of Patient Safety Netherlands & Hub Lead, **Bristol Myers Squibb**
132. **Maurizio Sessa**, Associate Professor, Pharmacovigilance and Pharmacoepidemiology, **University of Copenhagen**
133. **Rudi Scheerlinck**, Independent PV Expert
134. **TBC Job van Rest**, Team Lead Digital Health Solutions Team, **KNCV Tuberculosis Foundation**
135. **TBC Mansa Mbenga**, Team Lead, Treatment & Care, **KNCV Tuberculosis Foundation**
136. **Dieter Wetzl**, Head of Medical Science, **toclinco GmbH**
137. **Manni Kuthiala**, Associate Director, Clinical Safety, **Roche**
138. **TBC Edine Tiemersma**, Senior Epidemiologist, **KNCV Tuberculosis Foundation**
139. **TBC Sriram Venkateswaran**, Safety Data Science Director, **Roche**
140. **Ana Sofia Afonso**, Independent PV Expert
141. **Henry Barton**, Global Safety Lead, **Grünenthal Group**
142. **TBC Ajibade Adesina**, Director, PV Process Excellence & Learning Strategy, **Bristol Myers Squibb**
143. **Karin Kempe**, EU and UK QPPV, **Karo Healthcare**
144. **TBC Catherine Pons**, Director, Head of Pharmacovigilance, **Roche**
145. **Fredrik Grünenfelder**, Lead Patient Safety Physician, Mental Health & Eye Health, **Boehringer Ingelheim**
146. **Tasia-Leigh Deleon**, Senior Manager, Cosmetovigilance, **Chanel**
147. **Moin Don**, Lead, South Asia Chapter, **ISOp**
148. **Smruti Kothari**, Associate Director, Global Patient Safety, Quality and Compliance, **Regeneron**
149. **Tea Babic**, Director, Global Head of PV Audits and Inspections, Deputy Head PV Compliance, **Teva Pharmaceuticals**
150. **Robert Westphal**, Digital Lead, IT Pharma, Chief Medical Office, **Bayer**
151. **Ewa Malinowska**, Associate Director, Clinical Data Management, **MSD**
152. **Isabel Glauss**, Senior Clinical Data Engineer, **Boehringer Ingelheim**
153. **Monika Sarnecka**, Associate Director, Clinical Data Management, **MSD**
154. **Anna Wiczner**, Associate Director, Clinical Data Management, **MSD**
155. **Śława Janczewska**, Associate Director, Clinical Data Management, **MSD**
156. **Erika Barbarosie**, Associate Director, **Compliance**
157. **Monika Manske**, Lead Quality Management and Deputy EEA QPPV, **Viatis**
158. **TBC Ekaterina Edle von Dall'Armi**, Local QPPV, Germany, **GSK**
159. **TBC Myriam Salem**, National Good Pharmacovigilance Practices Inspection Program Coordinator, **Health Canada**
160. **Aimilia Nikolakaki**, Senior Manager, Safety Risk Lead, **Pfizer**
161. **TBC Marianne Banoub**, Regional Head, Quality & Pharmacovigilance, MENA Region, **NewBridge Pharmaceutical**
162. **György Zörényi**, Senior Medical Director, Medical Safety, **Jazz Pharmaceuticals**
163. **Mary Lynne Pomfret**, President, **World Federation for Incontinence and Pelvic Pain**
164. **Hadir Rostom**, Independent PV Expert & Lecturer, **Modern Sciences and Arts University**
165. **TBC Edine Tiemersma**, Senior Epidemiologist, **KNCV Tuberculosis Foundation**
166. **Tanja Hoffman**, Independent PV Expert
167. **Kieran O'Donnell**, Independent PV Expert
168. **Mircea Ciuca**, Independent PV Expert
169. **Joan D'souza**, Local QPPV & Independent PV Expert
170. **Kieran O'Donnell**, Independent PV Expert
171. **Ronald Boumans**, EU Medical Devices Expert and Former Inspector for Medical Devices
172. **Mina Awad**, Senior Pharmacovigilance Manager/ Middle East, **Kyowa Kirin**
173. **Tina Wirström**, Director, PSMF expert, EUQPPV Office, **Takeda**
174. **Eniko Barta-Kondas**, Head of Global Pharmacovigilance Operations, **Gedeon Richter**
175. **Sabine Poltermann**, IPS Lead – Risk Management, **Bristol Myers Squibb**
176. **Karolina Gaładyk**, Director of Global Data and Product Safety, **Elanco Animal Health**
177. **Mark Widdowson**, Senior Manager Digital Capabilities, **Bristol Myers Squibb**
178. **Kristof Ludvig**, Senior Pharmacovigilance Manager, **Gedeon Richter**
179. **Luiz Lima**, Vice President Head of Neuroscience TA GPS, **Ipsen**
180. **Talija Milosevic**, Director, Clinical Safety, Surgical Structural Heart, **Edwards Lifesciences**
181. **Xenia Michail**, Associate Director, EU PV Sub-Cluster Manager SEE/ LSO GR, CY & MT, **Teva Pharmaceuticals**
182. **Remco Diab**, Global Head Pharmacovigilance, Science and Medical Affairs (Senior Advisor)
183. **Viacheslav Turok**, Global QPPV, **Darnytisia**
184. **Zoltan Barna**, Manager of Global Pharmacovigilance Compliance Unit, **Gedeon Richter**
185. **Sujith Madhavan**, Medical Director, Global Safety Physician, **Jazz Pharmaceuticals**
186. **Peter Hjelmström**, Director/ CEO, **Uppsala Monitoring Centre**
187. **Nibedita Rath**, Scientific Director, **Open Source Pharma Foundation**
188. **Silvia Danesi**, Pharmacovigilance Inspector, **MHRA**
189. **Sophie Radicke**, Head of GPvP, **MHRA**
190. **Galyna Cordero**, QPPV, Head of Pharmacovigilance Department, Clinical Expert, **JSC Farmak**
191. **Olena Grebinnyk**, Quality Manager of Pharmacovigilance Department, **JSC Farmak**
192. **Rishi Chopra**, Executive Director, Global Head of RA & PV Affiliate & Partner Business, **CSL Behring**

193. **Arnav Desai**, Senior Specialist, Business Solutions Engineer, **Bristol Myers Squibb**
194. **Dilara Günbay**, Associate Director, Associate Director, Patient Safety, **Gilead**
195. **Punam Bharania**, Executive Medical Director, **Amgen**
196. **Tarik Messaoud**, Medical Director, Drug Safety, **Iovance Therapeutics**
197. **Arijit Patra**, Senior Principal Scientist, **UCB**
198. **Sara Montanari**, Director Pharmacovigilance Regulatory Affairs & Medical Affairs Quality Assurance, **Menarini Italy**
199. **Tom Organ**, Director Global Safety Scientist, **Ipsen**
200. **Erica Banco**, Associate Director Benefit Risk Management, **BioNTech SE**
201. **Daniela Di Cosmo**, Senior Safety Advisor, GVP Lead Auditor, **Ferring Pharmaceuticals**
202. **Branka Stojanovic**, Country Safety Lead Serbia and CBCs, QPPV, Senior Manager, **Pfizer**
203. **Giuseppe Violante**, Associate Director, PV System Governance & Intelligence, **Jazz Pharmaceuticals**
204. **Asha Dasarath**, Senior Manager, Global Regulatory Strategy, **Jazz Pharmaceuticals**
205. **Obulesh Medikurthi**, Global Head of Medical Safety and PV Operations – Oncology, **Menarini Stemline**
206. **Roel van Lieshout**, Associate Director, Pharmacovigilance, EU & UK QPPV, **Huvepharma**
207. **Yvonne Hausmann**, Director Global Pharmacovigilance – EU QPPV/ UK QPPV, **MSD Animal Health Innovation**
208. **Ankur Borkakoty**, Head – Safety Case Processing, **Novartis**
209. **Gayathri Subburaman**, Senior Director, Global Safety Lead, **Menarini Stemline**
210. **Ed Mingle**, Head DSPV, Innovation & Business Solutions, **Insmed**

Day 0 – Tuesday 22 September

Time	Workshop 1	Workshop 2	Workshop 3
14.00	Title TBC Tasia-Leigh Deleon, Manager, Cosmetovigilance, Chanel	Advancing PV in animal health Karen van der Velden, Head, Global Pharmacovigilance Operations, Boehringer Ingelheim Vetmedica Gillian Diesel, Director of Pharmacovigilance REMEA, Elanco Animal Health Blanca Berrocal Gonzalez, Head of Pharmacovigilance Compliance and International Engagement, Veterinary Medicines Directorate Yvonne Hausmann, Director Global Pharmacovigilance – EU QPPV/ UK QPPV, MSD Animal Health Innovation	Workshop Title x Robert Westphal, Bayer
15.00	If AI Is Everywhere, Why Isn’t Pharmacovigilance Simpler? Vivek Ahuja, Executive Vice President - Global Delivery Excellence, Strategy & Growth – Pharmacovigilance, Eversana	The role of RWE and data in patient safety Linda Harmark, Director, Drug Safety Research Unit	Workshop Title 
16.00	Inspection readiness Moin Don, Lead, South Asia Chapter, ISO Silvia Danesi, Pharmacovigilance Inspector, MHRA	Clinical Safety and AI Joan D’souza, Local QPPV & Independent PV Expert Balaji Malla, Head of Pharmacovigilance, EU & UK QPPV, Dr Reddy’s Elena Prokofyeva, Head of Drug Safety Unit, Department of R&D, Federal Agency for Medicines and Health Products, Belgium Sara Montanari, Director Pharmacovigilance Regulatory Affairs & Medical Affairs Quality Assurance, Menarini Italy Mircea Ciuca, Independent PV Expert Julia Appelskog, Head of QPPV Office, CSL	x Robert Westphal, Bayer
17.00 End of workshops			

Day 1 – Wednesday 23 September

08.00 Registration & Networking Meetings

08.50 Welcome
Katie O’Leary, Conference Producer, World Patient Safety Congress EU & US

08.55 Chair’s remarks
Mariette Boerstael, Senior Vice President, Worldwide Patient Safety Officer, Bristol Myers Squibb

Morning Plenary

09.00 Title TBC
Jens-Ulrich Stegmann, Senior Vice President, Head, Clinical Safety and Pharmacovigilance, EU QPPV, GSK

09.20 Title Sponsor: Connected Intelligence: How Agentic AI Is Transforming Life Sciences Operations
Aman Wasan, Chief Executive Officer, ArisGlobal



09.40 Fireside chat – Pharmacovigilance as an enabler of strategic value
Moderator: Tjark Reblin, Senior Vice President, Global Head of Patient Safety, Ipsen
Phil Tregunno, Deputy Director, Patient Safety Monitoring, MHRA
Fabian Heisig, Senior Vice President, Chief Medical Officer, Head Global Drug Safety & QPPV, Grunenthal

10.00 Diamond sponsor:



10.20 Title TBC
Serban Ghiorgiu, Deputy Chief Medical Officer, Chief Safety Officer, AstraZeneca

10.40 Diamond sponsor: Making Precision Pharmacovigilance Real: The Future Is Already Here
Sanjay Vyas, President, Safety & Logistics and Country Head of India, Parexel



11.00 Morning Break

Track 1	Track 2	Track 3	Track 4	Track 5	Track 6	Track 7	Track 8	Track 9	Track 10
ARTIFICIAL INTELLIGENCE	AUTOMATION	RISK MANAGEMENT	RISK MANAGEMENT 2	SIGNAL DETECTION & MAN- AGEMENT	QUALITY ASSURANCE	COMPLIANCE	PATIENT CENTRICITY	DIGITAL TRANSFORMATION	OUTSOURCING
11.15 Chair: Pav Rishiraj , Head of Phar- macovigilance, Celltrion	11.15 Chair: Sylvain Nicolas , Global Head, Safety Data Strategy and Data Management, Sanofi	11.15 Chair: Peter Kohut , Senior Direc- tor, Head of Pharmacovigi- lance, Alvotech	11.15 Chair: Joan D’souza , Local QPPV & Independent PV Expert	11.15 Chair: Fee Gedlich , Lead Patient Safety Physician, Cardiovas- cular and Established Prod- ucts, Boehringer Ingelheim	11.15 Chair: Delphine Bertram , Senior Director, Global Pharma- covigilance, QPPV, Pharming	11.15 Chair: Gloria Bustos , Global Head, Patient Safety, Vantive	11.15 Chair: Willemijn van der Spuij , Exec- utive Director Europe, Patient Safety International, Bristol Myers Squibb	11.15 Chair: Emma Outram , Group Head, Safety Data Acquisition, Roche	11.15 Chair:
11.20 CIOMI XIV guidelines for implementing AI in pharmacovigilance Giovanni Furlan , Head, Medical Safety Operations, Sandoz Germany	11.20	11.20 What’s truly person- alised medicine? Disrupting pharmacovigilance Michael von Forstner , Chief Scientific Officer, MedGenie	11.20 The power of inter- nalizing the scientific own- ership of periodic safety re- ports Pedro Caetano , Senior Safety Physician, Oncology, Global Patient Safety, Debi- opharm	11.20 The Signal Beneath the Data Sabine Poltermann , IPS Lead – Risk Management, Bristol Myers Squibb	11.20 Collaborating for suc- cessful inspections Mijal Chavda , Senior Direc- tor, Global Head of GxP In- spections & GVP Quality, Kyowa Kirin	11.20 Breaking silos: cross- functional synergy for pro- active safety issue commu- nication Francesca Dickins , Advisor, Medical Quality Organisa- tion, Eli Lilly & Aya Zaghloul , Associate Director, Global Patient Safety, Eli Lilly	11.20 Patient engagement in PV: Turning intent into im- pact Begum Benli Peker , Director, Head of Patient Safety Neth- erlands & Hub Lead, Bristol Myers Squibb	11.20 Pharmacovigilance Systems and Process Stand- ards (PS²) – a cross-industry initiative to foster innova- tion through standardiza- tion Jen Whitebrook , Senior Di- rector, PV & Regulatory Plat- forms Lead, CSL Behring & Karthick Sukumaran , Tech- nology Enablement Director, Intelligent Safety Automa- tion, Roche	11.20 How is AI impacting strategic workforce plan- ning in outsourcing? Annette Humes , Chief of Staff, Global Head of Safety Resource and Alliance Man- agement, Roche
11.40 Sponsor presentation Andy Beal , Global Market- ing Director, Safety & Regu- latory Compliance, R&DS, IQVIA 	11.40 Sponsor presentation 	11.40 The Next Chapter in Global Risk Management: Harmonize. Digitize. Transi- tion 	11.40 Sponsor presentation 	11.40 Sponsor presentation 	11.40 Sponsor presentation	11.40 AI in PV: excellent balance between compli- ance & efficiency Gabriele Piaton , Head of In- novation & Grants Strategy, ProductLife Group & Sophie Lequin , Global Service Line Lead – Literature, Product- Life Group 	11.40 Sponsor presentation	11.40 Sponsor presentation 	11.40 From Information to Action: The Role of Regula- tory Intelligence in Out- sourcing Vladimir Hrib , Global Drug Safety Associate & Project Manager, Arriello 
12.00 Designing AI models for LMICs Sanjeev Srivastav , Signal Management Lead, BioN- Tech	12.00 Reserved for applied analytics and ML in PV	12.00 Structured benefit- risk assessments: practical implementations of CIOMS XII one year on Kieran O'Donnell , Inde- pendent PV Expert	12.00 Areas to consider for risk management in early clinical safety discussions Mohamed Abdillahi , Senior Director, Risk Management, AstraZeneca	12.00 The Role of RWE in Modern Signal Manage- ment Gayathri Subburaman , Sen- ior Director, Global Safety Lead, Menarini Stemline	12.00 QA oversight over Non-Interventional Studies (including Post-Authoriza- tion Safety Studies) Pedro Gomes , Global Direc- tor, Pharmacovigilance Quality Assurance Lead, MSD	12.00 Compliance meets in- novation: leveraging AI for PV insights Julia Appelskog , Head of QPPV Office, CSL	12.00 Local PV resourcing Bolatito Abatan , Director, Global Patient Safety, Interna- tional Office, BeOne Medi- cines	12.00 PV system transfor- mation from a business per- spective Monika Sarnecka , Associate Director, Clinical Data Man- agement, MSD & Ewa Mali- nowska , Associate Director, Clinical Data Management, MSD	12.00 Outsourcing entire lit- erature review process on a global and local scale Maximilian Jacobs , Head of Vendor Management, Phar- macovigilance, Bayer
12.20 Can You Trust Agen- tic AI? Governing the Next Era of Pharmacovigilance Jason Bryant , Senior Vice President - Product Man- agement, AI, ArisGlobal 	12.20 Smarter pharma- covigilance: Embedding au- tomated QC to reduce re- work, cut costs, and ele- vate patient safety Francois Audibert , VP, US Operations, Vitrana – a Parexel Company 	12.20 Sponsor presentation 	12.20 Decentralized Exper- tise, Centralized Effi- ciency—Harmonizing Local PV Services Across Global Markets through process centralization and automa- tion Sophie Besset-Dangla , VP, Head of Global Pharma- covigilance, Cencora	12.20 Sponsor presentation 	12.20 Sponsor presentation	12.20 Sponsor presentation Reserved for Eliquent	12.20 Sponsor presentation Reserved for APCER	12.20 Sponsor presentation 	12.20 Outsourced Pharma- covigilance: Why It Still Feels Inconsistent – and How to Regain Control Dr Graeme Ladds , CEO & Owner, PharSafer® 
12.40 - Lunch									
13.40 – 14.40 Patient Safety Connect 1 Hour. 4 Partners. Optimal efficiency. A dedicated power-hour of pre-scheduled, 1:1 meetings designed to solve your specific challenges. - The Format: 4 x 15-minute meetings - The Goal: Rapid sourcing and partnership vetting - The Match: 100% double opt-in (AI-Powered) Matches are filling up fast. Head to the Patient Safety Connect platform now to accept your introductions and secure your spot.									
14.40 Panel Discussions									
Artificial Intelligence Panel 1 – ArisGlobal - From Potential to Trusted Adoption: Scaling Agentic AI in Pharmacovigilance Moderator: Lucinda Smith, Chief Safety Product Officer, ArisGlobal									
Regulatory Agency Panel 2 – Moderator: Elena Prokofyeva, Head of Drug Safety Unit, Department of R&D, Federal Agency for Medicines and Health Products, Belgium & Reserved for MHRA Rania Mouchantaf , Executive Director, Health Canada , Peter Hjelmröström , Director/ CEO, Uppsala Monitoring Centre									
Risk Management Panel 3 – Positioning safety as a strategic function in R&D through continuous safety surveillance, signal detection and benefit–risk management Moderator: Nicola Charpentier, Vice President, Head of Pharmacovigilance, BioNTech Petar Gjorgiev , Global Patient Safety Program Lead, Regeneron & Suzanne Foncin , Senior Scientific Director and Group Leader, Safety Evaluation and Risk Management, GSK & Mohamed Ali Kotal , EU-QPPV & Head QPPV Office, Sandoz & Klaudija Marijanovic Barac , Associate Vice President, EU QPPV, Eli Lilly, Sujith Madhavan , Medical Director, Global Safety Physician, Jazz Pharmaceuticals									

Risk Management 2 Panel 4 – ArcaScience – AI assisted benefit risk evaluations Moderator: ArcaScience									
Signal Detection & Management Panel 5 – The strategic role of patient safety organisations in drug development and in the market Moderator: Magnus Nord, Vice President, Global Patient Safety, Biopharma, AstraZeneca Dimitris Zampatis, Director, Product Patient Safety, Sandoz & Ludovic Apoux, Director Global Consumer Safety, Signal & Risk Management Lead, Haleon									
Quality Assurance Panel 6 – Inspection insights: lessons learned Moderator: Mijal Chavda, Senior Director, Global Head of GxP Inspections & GVP Quality, Kyowa Kirin Tea Babic, Director, Global Head of PV Audits and Inspections, Deputy Head PV Compliance, Teva Pharmaceuticals & Mette Stie Kallesøe, Head of Pharmacovigilance, QPPV, Hansa Biopharma & Silvia Danesi, Pharmacovigilance Inspector, MHRA & Roel van Lieshout, Associate Director, Pharmacovigilance, EU & UK QPPV, Huvepharma									
Compliance Panel 7 – Amendments of the EU implementation regulation 2025_1466: impacts on PSMFs and auditing Moderator: Monika Manske, Lead Quality Management and Deputy EEA QPPV, Viatis & Sean Burke, Executive Director, Regional Lead, International Pharmacovigilance, MSD & Tina Wirström, Director, PSMF expert, EUQPPV Office, Takeda									
Patient Centricity Panel 8 – Patient centric pharmacovigilance: driving innovation and engagement across drug development Moderator: Bogdana Balas, Group Medical Director, Late-Stage & Marketed Medicines Safety, Roche & Rishi Chopra, Executive Director, Global Head of RA & PV Affiliate & Partner Business, CSL Behring & Obulesh Medikurthi, Global Head of Medical Safety and PV Operations – Oncology, Menarini Stemline & Roger Mutter, Medical Safety Director, Alfasigma									
Digital Transformation Panel 9 – Ultragenic Research Moderator:									
Outsourcing Panel 10 – Moderator: Ilaria Grisoni, Executive Director, Head of EU & International Pharmacovigilance, QPPV Office and EEA QPPV, Jazz Pharmaceuticals Laura Paolo Boga, Senior Director, Head of Global Pharmacovigilance, UK & EU QPPV, Dompe & Valentina Mancini, Senior Director, Pharmacovigilance, EU & UK QPPV, Shionogi & Andrea Oliva, Head of Pharmacovigilance, Italy, Viatis & Maria Jose Reneses, Senior Director, Deputy EU QPPV and Head of PSMF Team, Takeda & Eniko Barta-Kondas, Head of Global Pharmacovigilance Operations, Gedeon Richter & Fabio Miceli, Director EU/UK QPPV, Norgine									
Track 1	Track 2	Track 3	Track 4	Track 5	Track 6	Track 7	Track 8	Track 9	Track 10
ARTIFICIAL INTELLIGENCE	AUTOMATION	RISK MANAGEMENT	RISK MANAGEMENT 2	SIGNAL DETECTION & MANAGEMENT	QUALITY ASSURANCE	COMPLIANCE	PATIENT CENTRICITY	DIGITAL TRANSFORMATION	OUTSOURCING
15.40 Chair: Yvonne Schäfer , Head of Patient Safety and Pharmacovigilance Systems Business Solutions, Boehringer Ingelheim	15.40 Chair: Attila Olah , Head of Global Patient Safety, Gedeon Richter	15.40 Chair: Luiz Lima , Vice President Head of Neuroscience TA GPS, Ipsen	15.40 Chair: Jamal Baig , Director, Drug Safety, MSD	15.40 Chair: Tom Organ , Director Global Safety Scientist, Ipsen	15.40 Chair: Tanja Hoffman , Independent PV Expert	15.40 Chair: Moin Don , Lead, South Asia Chapter, ISO P	15.40 Chair: Talija Milosevic , Director, Clinical Safety, Surgical Structural Heart, Edwards Lifesciences	15.40 Chair: Ricarda Berg , Head of Drug Safety & Local QPPV, Germany, GSK	15.40 Chair:
15.45 AI use cases in safety at Pfizer Magdalena Godula , Director, Regional Safety Platform Lead, Pfizer	15.45 Reskilling and upskilling AI & automation into the PV workforce Robert Westphal , Digital Lead, IT Pharma, Chief Medical Office, Bayer	15.45 Pharmacovigilance and interactions with legal affairs- practical tips Rudi Scheerlinck , Independent PV Expert	15.45 Risk management for advanced therapies Akhilesh Chamediya , Global Medical Director, Patient Safety Lead, Alexion & AstraZeneca	15.45 Safety assessments for geriatric populations Sutirtha Mukhopadhyay , Senior Associate Director, Patient Safety Physician, Boehringer Ingelheim	15.45 Quality assurance for combination products Ranjana Khanna , Global Director, GVP, QA, R&D Quality, BeOne Medicines	15.45 Local and global requirements for QPPVs in Europe and EMEA Stefanie Amend-Mall , Director, Patient Safety Europe, Sandoz	15.45 Immune-related adverse reactions – aspects on detection and treatment Dieter Wetzel , Head of Medical Science, toclinco GmbH	15.45 Lessons learned during change management for database transitions Ariane Stollenwerk , Head of Safety Central Europe & APAC, UCB	15.45 Insourcing as an operational model for PV Anna Wieczner , Associate Director, Clinical Data Management, MSD & Ślawa Janczewska , Associate Director, Clinical Data Management, MSD
16.05 Sponsor presentation 	16.05 Sponsor presentation 	16.05 Why Safety and Medical Affairs Collaboration Is the Key to Complex Launch Success Tristan Learoyd , Chief Business Officer, Axian Consulting & Mark Perrott , Managing Partner, Axian Consulting 	16.05 Safety Monitoring in Human Viral Challenge Studies: Key Differences Compared to Late-Phase Efficacy Trials. Jelle Klein , Medical Director, Clinical Pharmacology Unit, SGS Pharma & Rafael Smets , Head Medical Safety & Regulatory, SGS Pharma 	16.05 Sponsor presentation	16.05 Sponsor presentation	16.05 From Passive Reporting to Active Partnership: Reimagining Patient Centricity in PV. Aya Anis , PV vendor & Operation Manager, Baupharma 	16.05 Sponsor presentation	16.05 Sponsor presentation 	16.05 The Pharma / CRO Partnership: Ways to Work Together in Achieving a Common Goal Esther Aparicio , Team Manager Global Case Processing, PV, UBC & Michelle Dardeno , UBC 
16.25 Agents on a mission in PV Siva Kumar Buddha , Medical Director, Global Patient Safety, Amgen & Punam Bharania , Executive Medical Director, Amgen	16.25 From hype to habit: how PV teams really use AI Luis Guedes , Global Product Safety Science Lead, Sobi	16.25 Effective early benefit-risk architecture Alex Bica , Global Head of Early Development Safety, CSL	16.25 Practical experiences in navigating GVP XVI Rev 3 Rohan Mane , Director of Risk Management, Regeneron	16.25 Reserved for MHRA	16.25 The proactive management and assessment of quality risks Melanie Dullemon , PV Quality Management System Head, Sanofi	16.25 Seeking compliance efficiencies in PV activities for small to mid-sized companies Johanna Strandell , Director, Patient Safety, Camurus AB	16.25 What is the role of shared decision making for advancing patient safety? Mary Lynne Pomfret , President, World Federation for Incontinence and Pelvic Pain	16.25 Safety narrative and communication: more Netflix than pharmacology textbook Jost Leemhuis , Senior Patient Safety Partner and Global Business Lead, Roche	16.25 PV outsourcing in the Middle Region – challenges and updates Mina Awad , Senior Pharmacovigilance Manager/ Middle East, Kyowa Kirin
16.45 – 17.45 Patient Safety Connect 1 Hour. 4 Partners. Optimal efficiency. A dedicated power-hour of pre-scheduled, 1:1 meetings designed to solve your specific challenges. • The Format: 4 x 15-minute meetings • The Goal: Rapid sourcing and partnership vetting • The Match: 100% double opt-in Matches are filling up fast. Head to the Patient Safety Connect platform now to accept your introductions and secure your spot.									
ARTIFICIAL INTELLIGENCE	AUTOMATION	RISK MANAGEMENT	RISK MANAGEMENT 2	SIGNAL DETECTION & MANAGEMENT	QUALITY ASSURANCE	COMPLIANCE	PATIENT CENTRICITY	DIGITAL TRANSFORMATION	OUTSOURCING

17.45 Chair:	17.45 Chair:	17.45 Chair: Ana Sofia Afonso , Independent PV Expert	17.45 Chair:	17.45 Chair: Fabio De Gregorio , Vice President Global Patient Safety, TA Rare Diseases Head, Ipsen	17.45 Chair: Elena Keller , Director, PV, RA, Quality and Medical Operations, Local QPPV, Ipsen DACH	17.45 Chair: Daniela Di Cosmo , Senior Safety Advisor, GVP Lead Auditor, Ferring Pharmaceuticals	17.45 Chair:	17.45 Chair:	17.45 Chair: Zoltan Barna , Manager of Global Pharmacovigilance Compliance Unit, Gedeon Richter
17.50 From Promise to Proof: How Sanofi Operationalized Governed AI in Pharmacovigilance at Global Scale Updesh Dosanjh , Practice Leader, Pharmacovigilance Technology Solutions, IQVIA 	17.50 Automation in ICSR case processing - The evolution & the future Karthick Sukumaran , Director, Technology Enablement, Intelligent Safety Automation, Roche	17.50 Registries design optimization and aRMMs Zina Sadeq , Director, Regional PV and Alliance Management, UK QPPV, Amicus Therapeutics	17.50 Understanding trends on aggregated data for safety oversight in clinical trials Fredrik Grünenfelder , Lead Patient Safety Physician, Mental Health & Eye Health, Boehringer Ingelheim & Isabel Glauss , Senior Clinical Data Engineer, Boehringer Ingelheim	17.50 Signal detection for small to medium pharma Israel Gutierrez , Chief Medical Officer, TLR Therapeutics	17.50 Experiences of adverse drug reaction reporting and perceptions of additional monitoring among patients and healthcare professionals in Poland. Magdalena Niedzielko , Academic Teaching Assistant, Department of Experimental and Clinical Pharmacology, Medical University of Warsaw	17.50 Greece evolutionizes MAH - HCP safety communication for a more sustainable future Xenia Michail , Associate Director, EU PV Sub-Cluster Manager SEE/ LSO GR, CY & MT, Teva Pharmaceuticals	17.50 Speaker presentation	17.50 The Human-Machine Partnership: Upskilling the PV Workforce for an Automated Future Karolina Gaładyk , Director of Global Data and Product Safety, Elanco	17.50 TBC Kristof Ludvig , Senior Pharmacovigilance Manager, Gedeon Richter
18.10 Artificial intelligence for risk prediction and assessment Delphine Saragoussi , Head of Pharmacoepidemiology, Vaccines, Patient Safety & Pharmacovigilance, Sanofi	18.10 Learnings from the FDA's emerging drug safety technology program (EDSTP) Thomas Kuckuk , Head, Pharmacovigilance Systems Management, Novartis & Minhaj Obeidullah , Global Head, Governance and Risk, Novartis	18.10 Next-Generation risk management: integrating clinical expertise in mastering strategies for risk management across the product lifecycle Juan Daccach , Vice President, Global Product Safety, Merz Aesthetics	18.10 PV considerations for gene therapy clinical trials Aimilia Nikolakaki , Senior Manager, Safety Risk Lead, Pfizer	18.10 Signal Detection in Pharmacovigilance: specific challenges for a Generic Company Viacheslav Turok , Global QPPV, Darnytisia	18.10 Auditing the real-world effectiveness of risk management plans Gemma Sayers , Team Lead Quality Auditing (PV), R&D Quality Assurance, GSK	18.10 Regulatory & PV Compliance in the MENA Region: Challenges and Strategies Giuseppe Violante , Associate Director, PV System Governance & Intelligence, Jazz Pharmaceuticals & Asha Dasarath , Senior Manager, Global Regulatory Strategy, Jazz Pharmaceuticals	18.10 Speaker presentation	18.10 Speaker presentation	18.10 Impact of centralization to local affiliate Dilara Günbay , Associate Director, Associate Director, Patient Safety, Gilead

18.30 Close of conference and drinks reception

Day 2 – Thursday 24 September

08.50 **Welcome**
Katie O’Leary, Conference Producer, **World Patient Safety Congress EU & US**

08.55 **Chair’s remarks**

Morning Plenary

09.00 **Title TBC**
Jijo James, Chief Medical Officer, MedTech & Interventional Oncology, **Johnson & Johnson**

09.20 **Diamond sponsor**



09.40 **Fireside Chat: Bringing artificial intelligence into your PV operating model**
Moderator: Ed Mingle, Head DSPV, Innovation & Business Solutions, **Insmed**
Alaric Jackson, Chief Digital Officer, **PrimeVigilance** and **Ergomed Group**

10.00 **Diamond sponsor**



10.20 **Diamond sponsor**



10.40 **Keynote panel discussion – Capturing the data that matters: challenges for follow-up in pharmacovigilance**
Moderator: Vicki Edwards, Vice President, Pharmacovigilance Excellence & International QPPV, **AbbVie**
Stewart Geary, Global Safety Officer, **Eisai**
Sarah Vaughan, Head of Vigilance Operations, **MHRA**
Rania Mouchantaf, Executive Director, **Health Canada**

11.20 Morning Break

<u>Track 1</u>	<u>Track 2</u>	<u>Track 3</u>	<u>Track 4</u>	<u>Track 5</u>	<u>Track 6</u>	<u>Track 7</u>	<u>Track 8</u>	<u>Track 9</u>	<u>Track 10</u>
<u>ARTIFICIAL INTELLIGENCE</u>	<u>AUTOMATION</u>	<u>RISK MANAGEMENT</u>	<u>RISK MANAGEMENT 2</u>	<u>SIGNAL DETECTION & MANAGEMENT</u>	<u>QUALITY ASSURANCE</u>	<u>COMPLIANCE</u>	<u>PATIENT CENTRICITY</u>	<u>DIGITAL TRANSFORMATION</u>	<u>OUTSOURCING</u>
11.35 Chair: Nibedita Rath , Scientific Director, Open Source Pharma Foundation	11.35 Chair:	11.35 Chair: Sabine Poltermann , IPS Lead – Risk Management, Bristol Myers Squibb	11.35 Chair: Angela Schmidt-Mertens , EU QPPV & General Safety Officer, Eisai EMEA	11.35 Chair: Manni Kuthiala , Associate Director, Clinical Safety, Roche	11.35 Chair: Zoe Hamill , Senior Director, Global Development Quality Management, Regeneron	11.35 Chair:	11.35 Chair: Antonella Fretta , Senior Director, Aggregate Reporting Team Lead, Pfizer	11.35 Chair:	11.35 Chair:
11.40 Production experience of systems with agentic AI at Pfizer Marcin Kruk , Senior Director, Drug Safety Unit Regional Head, Europe, Africa & Middle East, Pfizer	11.40 Building efficiencies through AI in veterinary PV Blanca Berrocal Gonzalez , Head of Pharmacovigilance Compliance and International Engagement, Veterinary Medicines Directorate	11.40	11.40 Implementation complexity of additional risk minimization measures: from global to local Binh To , Patient Safety Europe Lead & Local QPPV, BeOne Medicines	11.40 Signal detection for rare diseases Lalitha Mahadavan , Vice President, Clinical Research and Patient Drug Safety, Amicus Therapeutics	11.40 Affiliate perspectives on PV inspections Joachim Vandepitte , Country Patient Safety Head, Novartis Belgium	11.40 Preparation for a product launch in pharmacovigilance Baseer Ahmed , Executive Director, Drug Safety and Pharmacovigilance, Ionis Pharma	11.40	11.40 Scaling Digital Impact in Patient Safety: An Integrated Approach Mark Widdowson , Senior Manager Digital Capabilities, Bristol Myers Squibb	11.40 Rethinking how a mid-sized pharma works with its PV tech and services vendor Howard Snow , Vice President, Global Head of Pharmacovigilance, Sobi

12.00 Sponsor presentation  An Ergomed company	12.00 Sponsor presentation  LIFE SCIENCES	12.00 Sponsor presentation	12.00 Sponsor presentation	12.00 Sponsor presentation	12.00 Sponsor presentation	12.00 Sponsor presentation	12.00 Sponsor presentation	12.00 Sponsor presentation 	12.00 Sponsor presentation Ieva Kupčiūnaitė, Senior Pharmacovigilance Specialist, QPPV Office, Insuvia 
12.20 Roche’s journey to agentic AI in pharma development Jorge Carmona, Global Product Line Lead (Head), Patient Safety Risk Management, Roche	12.20 Agentic AI for causality assessment Maurizio Sessa, Associate Professor, Pharmacovigilance and Pharmacoepidemiology, University of Copenhagen	12.20 The role of RWE and data in patient safety Linda Harmark, Director, Drug Safety Research Unit	12.20 Is Structured Benefit–Risk Assessment Beneficial in First-in-Human and Early-Phase Oncology Trials: A Must or a Nice-to-Have? György Zörényi, Senior Medical Director, Medical Safety, Jazz Pharmaceuticals	12.20 Signal, risk management and benefit-risk in OTC settings Paraskevi Floroskoufi, Regional PV Head, Europe and Eurasia, Opella & Yasmina Bouaziz , Signal & Risk Management Lead, Opella	12.20 CAPA management Erika Barbarosie, Associate Director, Compliance	12.20 Consolidated solutions for PV intelligence and PSMF management Nadine O’Hare, Senior Director, Global Patient Safety, PV Intelligence, Regeneron & Andrea van Poppe -Rosier, Associate Director, Global Patient Safety, QPPV Operations, GPS, Regeneron	12.20 Reflections on the representation of women in clinical trials from a safety perspective Catherine Tchinou, Head of Medical Safety, Biopharma, Sandoz	12.20 Speaker presentation	12.20 Making the most of change: maximizing the value and purpose Simon Ashworth, Global Head of Safety, Menarini
12.40 Explainability Does Not Equal Safety Beena Wood, Chief Product Officer, Qinecsa 	12.40 Sponsor presentation 	12.40 Sponsor presentation	12.40 Sponsor presentation	12.40 Sponsor presentation	12.40 Sponsor presentation	12.40 Sponsor presentation	12.40 Sponsor presentation	12.40 Sponsor presentation 	12.40 Sponsor presentation

13.00 Lunch

14.00 Patient Safety Connect
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15.00 Panel Discussions

Artificial Intelligence Panel 1 – Human + Machine: building trustworthy AI in drug safety
Moderator: **Claudia Lehmann**, Vice President, Head, Patient Safety & Pharmacovigilance Operations, **Boehringer Ingelheim**
Mark Daniels, Senior Director, Medical Safety, **Jazz Pharmaceuticals** & Siva Kumar Buddha, Medical Director, Global Patient Safety, **Amgen & Arijit Patra**, Senior Principal Scientist, **UCB**

Automation Panel 2 – AI & Automation for predictive safety: innovations for signal management
Moderator: **Teodora Perger**, Visiting Lecturer, Centre for Pharmaceutical Medicine Research, **King’s College London**
Marie-Laure Kurzinger, Head of Pharmacoepidemiology, General Medicine, **Sanofi**

Medical Devices Panel 3 – Current perspectives on safety approaches between pharmaceutical, medical devices, combination products & cosmetics
Moderator: **Juan Daccach**, Vice President, Global Product Safety, **Merz Aesthetics**
Tasia-Leigh Deleon, Senior Manager, Cosmetovigilance, **Chanel & Reserved for MHRA** & Judy Barretto, Senior Director, Virology TA, Patient Safety, **Gilead & Ronald Boumans**, EU Medical Devices Expert and Former Inspector for Medical Devices & **Maritess Esguerra**, Senior PV Process Director, **Genentech & Sylvie Bartus**, Senior Director, Clinical Safety Global, Clinical Affairs, Surgical Structural Heart, **Edwards Lifesciences**

Risk Management 2 Panel 4 – Risk management and communication in non-EU countries
Moderator: **Marjan Dzeeparoski**, RA & PV Manager, **Bionika Pharmaceuticals** & Lecturer, Medicine Faculty, **Goce Delčev University of Štip**
Branka Stojanovic, Country Safety Lead Serbia and CBCs, QPPV, Senior Manager, **Pfizer**

Signal Detection & Management Panel 5 – Sponsor
Moderator:

Quality Assurance Panel 6 – The changing landscape of PV inspections
Moderator: **Smruti Kothari**, Associate Director, Global Patient Safety, Quality and Compliance, **Regeneron**
Amy Ryan, Director, Patient Safety Inspection Excellence, **AstraZeneca & Sophie Radicke**, Head of GPvP, **MHRA & Hadir Rostom**, Independent PV Expert & Lecturer, **Modern Sciences and Arts University & Sara Montanari**, Director Pharmacovigilance Regulatory Affairs & Medical Affairs Quality Assurance, **Menarini Italy**

Compliance Panel 7 -
Moderator:

Patient Centricity Panel 8 – Emerging Businesses Sponsor Panel
Moderator: **Darko Krnic**, Director, Head of Medical Information & PV, **Pharma&**
Attila Csikász-Nagy, Commercial Development Lead, **Cytocast**

Women in PV Panel 9 –
Moderator: **Michelle Motta Dardeno**, Vice President, Head of Global Patient Safety, **Aurinia**
Dany Ward, Executive Director, Head of PV Ops & Global Risk Management, **Jazz Pharmaceuticals & Wivina De Waele**, Senior Director, Safety Lead Europe, Global Patient Safety, **AstraZeneca & Jolanda De Bruijne**, Senior Director, Head of PV Compliance, **Teva Pharmaceuticals & Karin Kempe**, EU and UK QPPV, **Karo Healthcare**

Outsourcing Panel 10 – Sponsor
Moderator:

Track 1	Track 2	Track 3	Track 4	Track 5	Track 6	Track 7	Track 8	Track 9	Track 10
ARTIFICIAL INTELLIGENCE	AUTOMATION	RISK MANAGEMENT	RISK MANAGEMENT 2	SIGNAL DETECTION & MANAGEMENT	QUALITY ASSURANCE	COMPLIANCE	PATIENT CENTRICITY	DIGITAL TRANSFORMATION	OUTSOURCING
16.00 Chair:	16.00 Chair:	16.00 Chair:	16.00 Chair:	16.00 Chair: Mircea Ciuca , Independent PV Expert	16.00 Chair:	16.00 Chair:	16.00 Chair:	16.00 Chair:	16.00 Chair:

16.05 Agent Enabled Automation to Streamline Global to Local RMP updates Mark Widdowson, Senior Manager Digital Capabilities, Bristol Myers Squibb & Arnav Desai, Senior Specialist, Business Solutions Engineer, Bristol Myers Squibb	16.05 Speaker presentation	16.05 Additional risk minimization measures in France Amir Lahouegue, Director, Patient Safety & Cluster Lead, France & Benelux, AstraZeneca	16.05 Balancing GVP requirements with HCP burdens Henry Barton, Global Safety Lead, Grünenthal Group	16.05 Speaker presentation Reserved	16.05 Speaker presentation	16.05 Beyond Compliance: Redefining QMS for the Future of Pharmacovigilance Ankur Borkakoty, Head – Safety Case Processing, Novartis	16.05 Trust not just tech Remco Diab, Global Head Pharmacovigilance, Science and Medical Affairs (Senior Advisor)	16.05 Speaker presentation	16.05 Speaker presentation
16.25 Speaker presentation	16.25 Speaker presentation	16.25 Risk Management Challenges for Complex and Innovative Therapies Tarik Messaoud, Medical Director, Drug Safety, Iovance Therapeutics	16.25 BRAP Taskforce Erica Banco, Associate Director Benefit Risk Management, BioNTech SE	16.25 Speaker presentation Reserved	16.25 Speaker presentation	16.25 Speaker presentation	16.25 Assessment of Adverse Drug Reactions and Causality Evaluation in Conditions of Chronic Stress: Emerging Challenges in the Current Context Galyna Cordero, QPPV, Head of Pharmacovigilance Department, Clinical Expert, JSC Farmak & Olena Grebinnyk, Quality Manager of Pharmacovigilance Department, JSC Farmak	16.25 Speaker presentation	16.25 Speaker presentation

16.45 Close of conference