

WORLD
DRUGSAFETY
CONGRESS EUROPE

World Drug Safety Europe Congress 2024

9-10th October 2024 – Amsterdam – Amsterdam RAI

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

1. **Serban Ghiorghiu**, Chief Safety Officer, **AstraZeneca**
2. **Patrick Caubel**, Chief Safety Officer, **Pfizer**
3. **Ira Solomon**, Chief Safety Officer, Innovation, **Johnson & Johnson**
4. **Fatima Bhayat**, Chief Safety Officer, Head of Global Patient Safety, **Amgen**
5. **Ercem Atillasoy**, Chief Regulatory and Safety Officer, **Jazz Pharmaceuticals**
6. **Felix Arellano**, Senior Vice President, Global Head of Pharmacovigilance and Drug Safety, **Roche**
7. **Mariette Boerstoeel Streefland**, Senior Vice President, Worldwide Patient Safety Officer, **Bristol Myers Squibb**
8. **Martine Zimmermann**, Senior Vice President, Head of Regulatory, R&D Quality, **Ipsen**
9. **Avinash Kakade**, Senior Vice President, Global Head of Pharmacovigilance, **Dr Reddy's Laboratories**
10. **Jens-Ulrich Stegmann**, Senior Vice President, Head Clinical Safety and Pharmacovigilance, EU QPPV, **GSK**
11. **Fabian Heisig**, Senior Vice President, Head Global Drug Safety & QPPV, **Grunenthal Group**
12. **Karsten Lollike**, Corporate Vice President, QPPV, **Novo Nordisk**
13. **Uwe Gudat**, Chief Medical Officer, **Biocon Biologics**
14. **Stewart Geary**, Global Safety Officer, **Eisai**
15. **Phil Tregunno**, Deputy Director, Patient Safety Monitoring, **Medicines & Healthcare Products Regulatory Agency**
16. **Peter Hjelmsström**, Director, **Uppsala Monitoring Center**
17. **Fabio Lievano**, Vice President, Safety Science, **AbbVie**
18. **Claudia Lehmann**, Vice President, Head, Patient Safety & Pharmacovigilance Operations, **Boehringer Ingelheim**
19. **Wasim Anwar**, Vice President, Deputy QPPV, **Novo Nordisk**
20. **Luiz Lima**, Vice President, Head of Neuroscience, Global Patient Safety, **Ipsen**
21. **Wally Landsberg**, Vice President, Global Head Medical Safety, **Kyowa Kirin**
22. **Deepa Venkataraman**, Vice President, Drug Safety and Pharmacovigilance, **Corcept Therapeutics**
23. **TBC Lisa Benaïse**, Vice President, Head of Pharmacovigilance, **Calliditas**
24. **Michelle Motta Dardeno**, Vice President, Head, Global Patient Safety, **Aurinia**
25. **TBC Steve Dingman**, Vice President, Head of Pharmacovigilance, **Immunogen**
26. **Sarah Freestone**, Vice President, Head of Pharmacovigilance and Device Safety, **UCB**
27. **Meenal Patwardhan**, Vice President, Medical Safety Evaluation & Safety Data Sciences, **AbbVie**
28. **Fabio De Gregorio**, Vice President, Head of Drug Safety Europe, **Shionogi BV**
29. **Asif Mahmood**, Vice President, Medical Safety & Pharmacovigilance, **AskBio**
30. **Mason Shih**, Vice President, Safety Science, **Biomarin**
31. **Lisa Lawrence-Miyasaki**, Vice President, Head of Pharmacovigilance, **Alumis**
32. **Juan Daccach**, Vice President, Global Product Safety, **Merz Aesthetics**
33. **Katherine Roberts**, Vice President, Global Pharmacovigilance, **Incyte**
34. **Pilar Carrero**, Vice President, Global Safety, **LEO Pharma**
35. **Attila Olah**, Vice President, Head, Global Patient Safety, EU-QPPV, **Gedeon Richter PLC**
36. **Jin Vermaat**, Vice President, Head PV Affiliate Relations, **Takeda**
37. **Irina Maria Ciubotaru**, Vice President, Head of Global Drug Safety and Pharmacovigilance, EU & UK QPPV, **ITM SE Isotopen Technologien Munchen**
38. **Peter De Veene**, Associate Vice President, Global QPPV, **MSD**
39. **Mohamed Ali Kotal**, Global Head, Medical Safety, **Sandoz**
40. **Stephanie Tcherny-Lessenot**, Global Head of Benefit Risk Evaluation, **Sanofi**
41. **Lucy Hampshire**, Associate Vice President, Head, Medicines Quality Organisation International, **Eli Lilly**
42. **Anastasia Ukhova**, Global Medical Head, Digital Healthcare, **Sanofi**
43. **Israel Gutierrez**, Chief Medical Officer, **TLR Therapeutics**
44. **Rishi Chopra**, Executive Director, Global Head of Pharmacovigilance, Regions, **CSL**
45. **Willemijn van der Spuij**, Executive Director, Worldwide Patient Safety International, **Bristol Myers Squibb**
46. **Ilaria Grisoni**, Executive Director, Head of EU & International Pharmacovigilance, QPPV Office and EEA QPPV, **Jazz Pharmaceuticals**
47. **Michael von Forstner**, Global Head, Safety Science, **Sobi**
48. **TBC Ilana Frishman**, Head of Drug Safety, **Compugen**
49. **TBC Koen Van der Heijden**, EU QPPV, **Galapagos**
50. **Arvind Bellur**, Executive Director, Head of PV Innovation and Transformation, **CSL Behring**
51. **Sunita Dhar**, Executive Medical Group Director, Clinical Safety, **Genentech**
52. **Frédérique Delannois**, Executive Director, Safety Evaluation & Risk Management Head, Global Safety, **GSK**

53. **Mijal Chavda**, Senior Director, Global Head of GxP Inspections & GVP Quality, **Kyowa Kirin**
54. **Jean-Christophe Delumeau**, Board Director, **Institute of Pharmacovigilance**
55. **TBC Sylvie Bartus**, Senior Director, Clinical Safety Global, Clinical Affairs, Surgical Structural Heart, **Edwards Lifesciences**
56. **Suzanne Foncin**, Senior Director, Head of Safety Analysis and Writing, **UCB**
57. **Rebecca Webb**, Senior Director, Safety, Vigilance and Medical Affairs QA, **AbbVie**
58. **Valentina Mancini**, Senior Director, Pharmacovigilance, EU & UK QPPV, **Shionogi Europe & TransCelerate**
59. **Alex Liede**, Senior Director, Global Epidemiology, **AbbVie**
60. **Asa Mattsson**, Senior Director, Patient Safety Risk Management, Process & Implementation, **AstraZeneca**
61. **Anand Ananthakrishnan**, Senior Director, Drug Safety and Pharmacovigilance, **Blueprint Medicines**
62. **Sean Burke**, Senior Director, Regional Lead, International Pharmacovigilance, **MSD**
63. **Heike von Treichel**, Senior Director, Deputy EU QPPV, Head of PV QMS, **Merck**
64. **Sibel Guerler**, Senior Director, Head of Innovation, Partnerships and Process Optimisation, WorldWide Patient Safety, **Bristol Myers Squibb**
65. **TBC Wivina De Waele**, Senior Director, Safety Lead Europe, Global Patient Safety, **Alexion**
66. **Marcin Marciniak**, Senior Director, Global Safety and PV Expert WHC, **Gedeon Richter**
67. **James Whitehead**, Senior Director, Devices & Digital Safety, **AstraZeneca**
68. **Laura Paolo Boga**, Senior Director, Head of Global Pharmacovigilance, UK & EU QPPV, **Dompe Farmaceutici**
69. **TBC Inge Jeding-Jansen**, Senior Director, Head of Global Pharmacovigilance, **ALK**
70. **Philip Jones**, Senior Director, Disease Area Cluster Lead, Inflammation & Immunology, **Pfizer**
71. **Antonella Fretta**, Senior Director, Aggregate Reporting Team Lead, **Pfizer**
72. **Gloria Bustos**, Senior Director, Head of Pharmacovigilance, EMEA & APAC / Global Patient Safety, **Baxter Healthcare**
73. **TBC Ellen Ravn Englev**, Senior Director, SO Processes & PV Technology, Safety Operations, Global Safety, **Novo Nordisk**
74. **TBC Maria Tello**, Senior Medical Director, Patient Safety & PV Lead, Strategy and Innovation, **Horizon Therapeutics**
75. **Bert Van Leeuwen**, Senior Director, Deputy QPPV, **Astellas**
76. **Elena Cucu**, Deputy EU and UK QPPV, **AbbVie**
77. **Raj Bhogal**, Senior Director, R&D Business Strategy & Operations, **Jazz Pharmaceuticals**
78. **Shaantanu Donde**, Senior Medical Director, Head of Portfolio Management Team, Clinical Development & Medical Affairs, **Viatri**
79. **Marcin Kruk**, Senior Director, Drug Safety Unit Regional Head, Europe, Africa & Middle East, **Pfizer**
80. **Marta Pujol**, Senior Director, Patient Safety, **AstraZeneca**
81. **Marina Suvakov**, Global Head Product, Safety Surveillance, **Phillip Morris International**
82. **Ranjana Khanna**, Global Director, GVP, QA, R&D Quality, **BeiGene**
83. **TBC Raphael Van Eemeren**, Senior Director, EU/UK QPPV, Global Patient Safety, **Amgen**
84. **Karine Palin**, Eu2P Programme Manager, **University of Bordeaux**
85. **Robert Massouh**, Head, Risk Management and Benefit-Risk Evaluation, **GSK**
86. **Sarah Vaughan**, Head of Vigilance Operations, **MHRA**
87. **Ibrahim Altamawy**, Medical Affairs & Compliance Regional Head, MENA, **SAJA Pharmaceuticals**
88. **TBC Maritess Esguerra**, Senior PV Process Director, **Genentech**
89. **Yvonne Nanciu**, Country Head, Pharmacovigilance, Deputy EU QPPV, **Bayer**
90. **Omar Aimer**, President, North American Chapter, **ISO**
91. **Judy Barretto**, Senior Global Process Director, Signal Management, **Roche**
92. **Robert Di Giovanni**, Senior Global Patient Safety Lead, **Novartis**
93. **Sutirtha Mukhopadhyay**, Senior Associate Director, Senior Patient Safety Physician, **Boehringer Ingelheim**
94. **Nibedita Rath**, Scientific Director, **Open Source Pharma Foundation**
95. **Julia Appelskog**, EU QPPV, Global Vaccine Safety, **Novavax**
96. **TBC Myriam Salem**, Pharmacovigilance Manager, **Health Canada**
97. **Garry Floudners**, Global Pharmacovigilance Operations Lead, Biosimilars, **Biogen**
98. **TBC Ana Sofia Afonso**, Director, Pharmacoepidemiology, Global Patient Safety, **Eli Lilly**
99. **Emma Boulton**, Director, Safety Operations, **Mundipharma**
100. **John Hart**, Director, EEA & UK QPPV, **Samsung Bioepis**
101. **Riti Shah**, Medical Director, Pharmacovigilance, **Chiesi Group**
102. **TBC Amar Swaroop**, Director, Global Lead, Customer Engagement Programmes, **Viatri**
103. **Laura Pasetti**, Director, Aggregate Reporting Author, **Pfizer**
104. **Kristin Knaalstad**, Director, Risk Management, Patient Safety, **AstraZeneca**
105. **Markus Drumm**, Head of Global Patient Safety Regions, **Merck**
106. **TBC Gabrielle Amselem**, Director, Patient Safety Excellence, **Alexion, AstraZeneca Rare Disease**

107. **Nawal Jebbar**, Lead, Safety and Pharmacovigilance, EMEA & EU QPPV, **Amylyx Pharmaceuticals**
108. **Priyadarshani Dharia**, Director, Global Safety Epidemiology, Real World Evidence, **Moderna**
109. **Tea Babic**, Director, Global Head of PV Audits and Inspections, Deputy Head PV Compliance, **Teva Pharmaceuticals**
110. **Giovanni Furlan**, Director, Worldwide Safety Site Lead, **Pfizer**
111. **Carrie Scott**, Head of Global PV Compliance and Policy, **AbbVie**
112. **Cristina Hentea**, Director, Safety Surveillance and Risk Management, **Viartis**
113. **Vivienne van de Walle**, Medical Director, **PT&R**
114. **Milos Stojkovic**, Safety Process Director, **Roche**
115. **Mattia Calissano**, Director, Head of Pharmacovigilance, **Orchard Therapeutics**
116. **Tarak Thakker**, Director, Head of Safety Systems and Analytics, **BeiGene**
117. **Andrew Moore**, Director, PV Operations and Compliance, **Takeda**
118. **Jaylaxmi Nalawade**, Director, Pharmacovigilance and REMS, **Lupin Inc**
119. **Gemma Sayers**, Director, Pharmacovigilance Quality Management Lead, **Regeneron**
120. **Marco Tuccori**, Pharmacovigilance Manager and Coordinator, **University Hospital of Pisa & Tuscan Regional Centre of Pharmacovigilance**
121. **Anne Raison**, Head of Quality and Medical Compliance Management, **Roche**
122. **TBC Jefferson Guillon**, Director, UK QPPV, **Seqirus**
123. **Marco Colombati**, PV Operations Manager, **ITALFARMACO SPA**
124. **Tommaso Venturi**, Global Pharmacovigilance Risk Evaluation Specialist, **ITALFARMACO SPA**
125. **TBC Donia Al-Bastaky**, Head of Drug Safety, **Kuwait Health Authority**
126. **TBC Darren Stewart**, Chief Experience Officer, Competency Accelerator, **Roche**
127. **TBC Balaji Malla**, Head of Pharmacovigilance, EU & UK QPPV, **Dr Reddy's Laboratories**
128. **George P. Patrinos**, Professor, Department of Pharmacy, **University of Patras & Adjunct Professor, Department of Genetics and Genomics, United Arab Emirates University**
129. **Lynne Comiskey**, PV Regions Divestment Coordination Lead, **Sanofi**
130. **Rudi Scheerlinck**, Safety Strategy Lead, **Merck Healthcare Oncology**
131. **Ariane Stollenwerk**, Director, Head of Central Europe & Asian Int. Markets, International PhV, **UCB**
132. **Minhaj Obeidullah**, Director, Head, Compliance and Risk Management, **Novartis**
133. **TBC Barta-Kondas Eniko**, Head, Global PV Operations, **Gedeon Richter**
134. **Elisabetta Di Martino**, Director, GCP, GVP & GLP, Quality Assurance, **Orchard Therapeutics**
135. **Daniela Di Cosmo**, Senior Safety Advisor, Global Safety, **Ferring**
136. **Emmanuelle Pines**, Head of Safety Policy & Process Oversight, QPPV Office, **Janssen**
137. **Mina G Awad**, Pharmacovigilance Senior Manager and QPPV, Middle East, **Kyowa Kirin International**
138. **TBC Isabella Caramuta**, Deputy QPPV, Pharmacovigilance Manager, **Shionogi Europe**
139. **TBC Anna Pelnikovich**, Director, Head, Project Management and Periodic Safety Reports, **Merck**
140. **Maria Jose Reneses**, Director, Deputy EU QPPV and Head of PSMF, **Takeda**
141. **Monika Zych**, Director, Pharmacovigilance, ECEMEA, **Baxter Corp**
142. **Peter Kohut**, Director, Pharmacovigilance, **Alvotech**
143. **Jost Leemhuis**, Safety Science Partner and Global Business Lead, **Roche**
144. **Claudia Pierleoni**, Director, Global Safety Surveillance, **LEO Pharma**
145. **Akhilesh Chamediya**, Director, Senior Medical Expert, EU QPPV, **AiCuris**
146. **TBC Klaus Bitsch-Jensen**, Director, Head of QPPV Office, EU QPPV, **ALK**
147. **Marianne Mounir**, Senior Global System Auditor, **Bayer**
148. **Kishore Saha**, Chief Specialist, **Lundbeck**
149. **Leith Kwaan**, QPPV, **National Bioproducts Institute**
150. **Reinhold Schilling**, Head of Global Pharmacovigilance, EU QPPV, **Worwag Pharma**
151. **Katarzyna Gruchala**, Director, PV Operations Global Submissions, **Moderna**
152. **Jessica Marlind Wurtele**, Director, Patient Safety Excellence, **AstraZeneca**
153. **Teresa Saragoca**, Director, Regulatory Affairs & Technical Manager, **ITALFARMACO**
154. **TBC Anna Karin Traff**, Director, ICSR Lead, **AstraZeneca**
155. **Justyna Amelio**, Director, Global Epidemiology, **AbbVie**
156. **Vivien Stettner**, International PV Operational Excellence Lead, **AbbVie**
157. **Tsambika Fuchs**, Team Lead PV Intelligence and Performance Management, **Merck**
158. **Maha Elluri**, Global Safety Director, EU QPPV, **Indivior Pharma**
159. **Ludovic Apoux**, Global Signal Management Lead, **Haleon**
160. **Barbara Bovy**, Director, Head, Auditing and Compliance, Early Development, **UCB**

161. **Achilleas Kalogirou**, Lead, Office of Safety Operations, **Abbvie**
162. **Richard Mayer**, Senior Principal Engineer, Head of Medical Safety R&D, **Johnson & Johnson**
163. **TBC Julia Pfaff**, Head of Pharmacovigilance, QPPV, **Merz Therapeutics**
164. **TBC Ulrike Meyer**, Head of Product Safety, **Merz Therapeutics**
165. **Begum Benli Peker**, Director, Head of Patient Safety Netherlands & EU Hub Lead, **Bristol Myers Squibb**
166. **Pav Rishiraj**, Director, Head of Patient Safety, **Ipsen & ABPI** PV Expert Chair
167. **TBC Petra Lerner-Hiller**, PV Quality and QPPV Relations Lead, Deputy QPPV, **Merck**
168. **TBC Jan Cleerbout**, Deputy EU QPPV, QPPV Office, **Janssen**
169. **James Eldridge**, Director, Global Safety Surveillance, **Y-mAbs**
170. **TBC Ajibade Adesina**, Director, PV Process Excellence and Learning Strategy, **Bristol Myers Squibb**
171. **TBC Majken Berghuis**, Director, Pharmacovigilance, International Operations, **Novo Nordisk**
172. **TBC Phillip Eichorn**, Global Head of Drug Safety, **Amryt Pharma**
173. **Adeniyi Olagunju**, Tenure Track Fellow, Department of Pharmacology & Therapeutics, **University of Liverpool**
174. **Monika Manske**, Associate Director, Lead Quality Management and Deputy EEA QPPV, **Viartis**
175. **Ricarda Berg**, Associate Director, Head of Pharmacovigilance, DACH Region, International Pharmacovigilance, **Biogen**
176. **Marko Strott**, Associate Director, Partnership Management, Global Patient Safety, **Merck**
177. **Erika Barbarosie**, Associate Director, Compliance, **Gilead Sciences**
178. **Ben Kitchens**, Associate Director, Medical Devices, Diagnostics Lead, **Otsuka**
179. **TBC Olga Panek-Bialkowska**, Associate Director, Global Pharmacovigilance Case Management, **MSD**
180. **Jenny Griffiths**, Senior Principal Associate, Medicines Quality Organisation, **Eli Lilly & Co**
181. **TBC Janni Hermansen**, Head, Global Safety Surveillance, Biologics & Devices, **Leo Pharma**
182. **Conny Johansson**, Alliance Management Lead, **Roche**
183. **David Chonzi**, Independent PV Expert
184. **Ronald Boumans**, Independent Medical Device Expert
185. **Dimitris Zampatis**, Global Program Safety Lead, Global Patient Safety, **Sandoz**
186. **TBC Linda Bech**, Associate Director, Head of Patient Safety Nordics, **Gilead Sciences**
187. **Smruti Kothari**, Associate Director, PV QA, **Jazz Pharmaceuticals**
188. **Siva Kumar Buddha**, Senior Manager, Global Pharmacovigilance Physician, **Teva Pharmaceuticals**
189. **Diane Halle**, Senior Manager, Pharmacovigilance Quality Assurance, **Alnylam**
190. **Joan D'souza**, Independent PV Expert
191. **Jutta Syha**, Independent PV Expert
192. **Kieran O'Donnell**, Independent PV Expert
193. **TBC Heinz Weidenthaler**, Vaccine Pharmacovigilance Expert

Day 1 – Wednesday 9th October 2024

08.55 Chair's remarks

Mariette Boerstool Streefland, Senior Vice President, Worldwide Patient Safety Officer, Bristol Myers Squibb

Morning Plenary

09.00 Keynote presentation

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

09.20 Title Sponsor



09.40 Keynote presentation

Serban Ghiorghiu, Chief Safety Officer, AstraZeneca

10:00 Diamond sponsor



10.20 Enhancing medicines safety through external databases and artificial intelligence

Felix Arellano, Senior Vice President, Global Head of Pharmacovigilance and Drug Safety, Roche

10.40 Diamond presentation



11.00 Morning Break

Track 1	Track 2	Track 3	Track 4	Track 5	Track 6	Track 7	Track 8	Track 9	Track 10
AI + AUTOMATION	RISK MANAGEMENT	SIGNAL DETECTION & MANAGEMENT	QUALITY ASSURANCE	COMPLIANCE	CASE PROCESSING	MEDICAL DEVICES	PATIENT CENTRICITY	DIGITAL TRANSFORMATION	PV OUTSOURCING
11.40 Chair: Peter De Veene , Associate Vice President, Global QPPV, MSD	11.40 Chair: AXIAN 	11.40 Chair: Stewart Geary , Global Safety Officer, Eisai	11.40 Chair: Lucy Hampshire , Associate Vice President, Head, Medicines Quality Organisation International, Eli Lilly & Co	11.40 Chair: Gloria Bustos , Senior Director, Head of Pharmacovigilance, EMEA & APAC / Global Patient Safety, Baxter Healthcare	11.40 Chair: Garry Flounders , Global Pharmacovigilance Operations Lead, Biosimilars, Bio-gen	11.40 Chair: Sarah Freestone , Vice President, Head of Pharmacovigilance and Device Safety, UCB	11.40 Chair: Wally Landsberg , Vice President, Global Head Medical Safety, Kyowa Kirin	11.40 Chair: Pilar Carrero , Vice President, Global Safety, LEO Pharma	11.40 Chair: Rita Lobatto , Vice President, Pharmacovigilance & QPPV, Pharming Group
11.45 AI in pharmacovigilance of orphan medications Michael von Forstner , Global Head, Safety Science, Sobi	11.45 Speaker presentation AXIAN PHARMA SPEAKER	11.45 Connecting signal management and benefit-risk assessments Dimitris Zampatis , Global Program Safety Lead, Global Patient Safety, Sandoz	11.45 Preparation for inspection readiness: working with multicultural stakeholders Mijal Chavda , Senior Director, Global Head of GxP Inspections & GVP Quality, Kyowa Kirin	11.45 Medical reviews of ICSRs: case studies from FDA Riti Shah , Medical Director, Pharmacovigilance, Chiesi USA	11.45 Delegating and verifying case processing: diverging regulatory requirements and harmonizing best practices Nancy Dubois , Senior Director, Head of Global Patient Safety, Local Patient Safety Officer, US Region, EMD Serono	11.45 Novel signal detection methods for medical devices Sarah Vaughan , Head of Vigilance Operations, MHRA	11.45 Pharmacovigilance systems in Africa: advancing global health goals Marcin Kruk , Senior Director, Drug Safety Unit Regional Head, Europe, Africa & Middle East, Pfizer	11.45 Innovation ecosystems within pharmacovigilance James Whitehead , Senior Director, Device & Digital Safety, AstraZeneca	11.45 What successful outsourcing can look like in small pharma Lisa Lawrence-Miyasaki , Vice President, Head of Pharmacovigilance, Alumis
12.05 Sponsor presentation 	12.05 Sponsor presentation AXIAN	12.05 Sponsor presentation 	12.05 Sponsor presentation 	12.05 Sponsor presentation 	12.05 Sponsor presentation 	12.05 Sponsor presentation 	12.05 Sponsor presentation	12.05 Sponsor presentation 	12.05 Sponsor presentation
12.25 PharmaVigiPredict: A pilot, predictive surveillance model in pharmacovigilance using artificial intelligence Meenal Patwardhan , Vice President, Medical Safety Evaluation & Safety Data Sciences, AbbVie	12.25 Speaker presentation AXIAN PHARMA SPEAKER	12.25 Signal management for AAV gene therapies: advancements and challenges Mason Shih , Vice President, Safety Science, Biomarin	12.25 Regulatory challenges in quality assurance: producing guidance for the public sector Marco Tuccori , Pharmacovigilance Manager and Coordinator, University Hospital of Pisa & Tuscan Regional Centre of Pharmacovigilance	12.25 Building compliance oversight in PV systems Irina Maria Ciubotaru , Vice President, Head of Global Drug Safety and Pharmacovigilance, EU/UK QPPV, ITM SE Isotopen Technologien Munchen	12.25 Establishing case processing and compliance in social media in small and medium sized enterprises Reinhold Schilling , Head of Global Pharmacovigilance, EU QPPV, Worwag Pharma	12.25 Title TBC Sylvie Bartus , Senior Director, Clinical Safety Global Clinical Affairs, Surgical Structural Heart, Edwards LifeSciences	12.25 Benefit risk assessments for patients Stephanie Tcherny-Lessener , Global Head, Benefit-Risk Evaluation, Sanofi	12.25 Assessment of digital health in post market safety – an industry and regulatory landscape Barbara Bovy , Director, Head, Auditing and Compliance, Early Development, UCB	12.25 New models for outsourcing case management: working with ESPs to build processes Minhaj Obeidullah , Director, Head, Compliance and Risk Management, Novartis
12.45 Sponsor presentation 	12.45 Sponsor presentation AXIAN	12.45 Sponsor presentation	12.45 Sponsor presentation 	12.45 Sponsor presentation 	12.45 Sponsor presentation 	12.45 Sponsor presentation 	12.45 Sponsor presentation 	12.45 Sponsor presentation 	12.45 Sponsor presentation

13.05 Applications and innovations of AI in signal management Philip Jones , Senior Director, Disease Area Cluster Lead, Inflammation & Immunology, Pfizer	13.05 Speaker presentation AXIAN PHARMA SPEAKER	13.05 Signal detection understanding similarities: medical devices, vaccines and drugs Israel Gutierrez , Chief Medical Officer, TLR Therapeutics	13.05 Building a delegation profile for QPPVs Heike von Treichel , Senior Director, Deputy EU QPPV, Head of PV QMS, Merck	13.05 Driving a compliant culture through the QPPV office Jessica Marlind Wurtele , Director, Patient Safety Excellent, AstraZeneca	13.05 Speaker presentation	13.05 Changing legislation across geographies for medical devices Judy Barretto , Senior Global Process Director, Signal Management, Roche	13.05 Driving patient centrality in pharmacovigilance at a country level Yvonne Nanciu , Country Head, Pharmacovigilance, Deputy EU QPPV, Bayer	13.05 The future of the PV industry in the next 10 years Mohamed Ali Kotal , Global Head, Medical Safety, Sandoz	13.05 Transforming local safety roles Begum Benli Peker , Director, Head of Patient Safety Netherlands & EU Hub Lead, Bristol Myers Squibb
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13.25 Lunch

14.25 Interactive Panels

AI & Automation Panel 1 – Innovating in automation: diverse perspectives across the PV industry

Moderator: Deepa Venkataraman, Vice President, Drug Safety and Pharmacovigilance, **Corcept Therapeutics**

Uwe Gudat, Chief Medical Officer, **Biocon Biologics & Claudia Lehmann**, Vice President, Head, Patient Safety & Pharmacovigilance Operations, **Boehringer Ingelheim & Arvind Bellur**, Executive Director, Head of PV Innovation and Transformation, **CSL Behring**

Risk Management Panel 2 – Benefit risk management and assessments: engaging patients

Moderator: Luiz Lima, Vice President, Head of Neuroscience, Global Patient Safety, **Ipsen**

Sunita Dhar, Executive Medical Group Director, Clinical Safety, **Genentech & Marcin Marciniak**, Senior Director, Global Safety and PV Expert WHC, **Gedeon Richter**

Signal Detection & Management Panel 3 – Safety related posts to agency websites and submissions excluding label updates

Moderator: Sean Burke, Senior Director, Regional Lead, International Pharmacovigilance, **MSD**

Jean-Christophe Delumeau, Board Director, **Institute of Pharmacovigilance & Willemijn van der Spuij**, Executive Director, International Patient Safety, **Bristol Myers Squibb**

Quality Assurance Panel 4 – Behind the curtains of inspections: recent advances in GVP inspections

Moderator: Raj Bhogal, Senior Director, R&D Business Strategy & Operations, **Jazz Pharmaceuticals**

Tea Babic, Director, Global Head of PV Audits and Inspections, Deputy Head PV Compliance, **Teva Pharmaceuticals & Marianne Mounir**, Senior Global System Auditor, **Bayer**

Compliance Panel 5 – Global oversight for diverging regulations and business partners: harmonizing stakeholders

Moderator: Marco Colombati, PV Operations Manager, **ITALFARMACO SPA**

Michelle Motta Dardeno, Vice President, Head, Global Patient Safety, **Aurinia**

Compliance Panel 6 – Continuous improvement in vendor management compliance

Moderator:

Emmanuelle Pines, Head of Safety Policy & Process Oversight, QPPV Office, **Janssen & Anne Raison**, Head of Quality and Medical Compliance Management, **Roche France & Diane Halle**, Senior Manager, Pharmacovigilance Quality Assurance, **Alnylam**

Medical Devices Panel 7 - Different safety approaches between pharma, devices, and combination products

Moderator: Juan Daccach, Vice President, Global Product Safety, **Merz Aesthetics**

Omar Aimer, President, North American Chapter, **ISO P & Peter Kohut**, Director, Pharmacovigilance, **Alvotech**






Reserved Panel 8 – EVERSANA


Digital Transformation Panel 9 - Managing digital health – what are the considerations when implementing digital health to advance safety?

Moderator: James Whitehead, Senior Director, Devices & Digital Safety, **AstraZeneca**

Phil Tregunno, Deputy Director, Patient Safety Monitoring, **Medicines & Healthcare Products Regulatory Agency & Barbara Bovy**, Director, Head, Auditing and Compliance, Early Development, **UCB & Anastasia Ukhova**, Global Medical Head, Digital Healthcare, **Sanofi**

Reserved Panel 10 – ArisGlobal

AI + AUTOMATION	RISK MANAGEMENT	SIGNAL DETECTION & MANAGEMENT	QUALITY ASSURANCE	COMPLIANCE	CASE PROCESSING	MEDICAL DEVICES	PATIENT CENTRICITY	DIGITAL TRANSFORMATION	PV OUTSOURCING
15.10 Chair:	15.10 Chair:	15.10 Chair: Mattia Calissano , Director, Head of Pharmacovigilance, Orchard Therapeutics	15.10 Chair: Jutta Syha , Independent PV Expert	15.10 Chair: Wasim Anwar , Vice President, Deputy QPPV, Novo Nordisk	15.10 Chair:	15.10 Chair:	15.10 Chair: James Eldridge , Director, Global Safety Surveillance, Y-mAbs	15.10 Chair: Attila Olah , Vice President, Head, Global Patient Safety, EU-QPPV, Gedeon Richter PLC	15.10 Chair: Emma Boulton , Director, Safety Operations, Mundipharma
15.15 Automation in aggregate reporting with the help of AI Robert Di Giovanni , Senior Global Patient Safety Lead, Novartis	15.15 Safety profiling of medicinal products Tommaso Venturi , Global Pharmacovigilance Risk Evaluation Specialist, ITALFARMACO SPA	15.15 Integration of real-world data into signal management Siva Kumar Buddha , Global Pharmacovigilance Physician, Senior Manager, Teva Pharmaceuticals	15.15 The changing landscape of PV inspections Smruti Kothari , Associate Director, PV QA, Jazz Pharmaceuticals	15.15 Compliance metrics for vendors and partners in MENA region Mina G Awad , Pharmacovigilance Senior Manager and QPPV, Middle East, Kyowa Kirin International	15.15 Monitoring compliance in case processing Katarzyna Gruchala , Director, PV Operations Global Submissions, Moderna	15.15 Companion diagnostics at the point of care George P. Patrinos , Professor, Department of Pharmacy, University of Patras & Adjunct Professor , Department of Genetics and Genomics, United Arab Emirates University	15.15 Integrating patient voices in risk minimization measures Robert Massouh , Head, Risk Management and Benefit-Risk Evaluation, GSK	15.15 Continuing the innovation journey in Moderna: clinical trials and case processing Monika Kowalska , Director, Global Case Management, Moderna	15.15 Different partners and providers for PV outsourcing Juri Hodisch , Head, Drug Safety, QPPV, AOP Health
15.35 Sponsor presentation 	15.35 Developing Risk Management Plans for Cell and Gene Therapies Vineet Kacker , Managing Director, APCER Life Sciences 	15.35 Sponsor presentation 	15.35 Sponsor presentation	15.35 Sponsor presentation	15.35 Sponsor presentation	15.35 Sponsor presentation	15.35 Sponsor presentation	15.35 Sponsor presentation 	15.35 Sponsor presentation 

15.55 Machine learning and emerging technologies in patient safety Sibel Guerler , Senior Director, Head of Innovation, Partnerships and Process Optimisation, World-Wide Patient Safety, Bristol Myers Squibb	15.55 Variated control distribution systems for biosimilars: managing risk minimization John Hart , Director, EEA & UK QPPV, Samsung Bioepis	15.55 Safety management in phase 1 studies Sutirtha Mukhopadhyay , Senior Associate Director, Senior Patient Safety Physician, Boehringer Ingelheim	15.55 PV audits: pitfalls for the oversight of distributors Hadir Rostom , Independent PV Expert & Lecturer, Faculty of Pharmacy, Modern Sciences and Arts University	15.55 Involvement for partnership management in Merck Healthcare Marko Strott , Associate Director, Partnership Management, Global Patient Safety, Merck	15.55 Speaker presentation	15.55 Gaps in regulations for drug device combinations Joan D'souza , Independent PV Expert	15.55 RA and safety joining forces for patient centrality Markus Drumm , Head of Global Patient Safety Regions, Merck	15.55 Challenges in using social media for pharmacovigilance Ricarda Berg , Associate Director, Head of Pharmacovigilance, DACH Region, International Pharmacovigilance, Bio-Gen	15.55 Transitions in PV outsourcing: case processing and safety databases Anand Ananthkrishnan , Senior Director, Drug Safety and Pharmacovigilance, Blueprint Medicines
16.15 Networking Break									
AI + AUTOMATION	RISK MANAGEMENT	SIGNAL DETECTION & MANAGEMENT	QUALITY ASSURANCE	COMPLIANCE	CASE PROCESSING	MEDICAL DEVICES	PATIENT CENTRICITY	DIGITAL TRANSFORMATION	PV OUTSOURCING
16.45 Chair:	16.45 Chair:	16.45 Chair: Leith Kwaan , QPPV, National Bioproducts Institute	16.45 Chair:	16.45 Chair:	16.45 Chair:	16.45 Chair:	16.45 Chair:	16.45 Chair:	16.45 Chair:
16.50 AI safety systems and analytics: innovations for mid-sized biotech companies Tarak Thakker , Director, Head of Safety Systems and Analytics, BeiGene	16.50 Structured benefit risk assessments Marta Pujol , Senior Director, Patient Safety, AstraZeneca	16.50 Safety monitoring in clinical studies Rudi Scheerlinck , Safety Strategy Lead, Merck Healthcare Oncology	16.50 Risk-based auditing, from planning to closure Rebecca Webb , Senior Director, Safety, Vigilance and Medical Affairs QA, AbbVie	16.50 Being inclusive at global level: ensuring compliance in Taiwan and Korea Ariane Stollenwerk , Director, Head of Central Europe & Asian Int. Markets, International PhV, UCB	16.50 Speaker presentation	16.50 Software as a medical device: SaMD Ben Kitchens , Associate Director, Medical Devices, Diagnostics Lead, Otsuka	16.50 Enhancing PV education across HCPs: Implementation of an online PV course for pharmacists in Romania - a joint initiative Elena Cucu , Deputy EU and UK QPPV, AbbVie	16.50 iVigilance: aligning digital transformation and regulations with local LSRs Ibrahim Altamawy , Medical Affairs & Compliance Regional Head (MENA), SAJA Pharmaceuticals	16.50 Outsourcing of strategic PV activities Conny Johansson , Alliance Management Lead, Roche
17.10 Sponsor presentation  TRANSPERFECT	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation
17.30 NLP system performance evaluation and analysis Marina Suvakov , Global Head Product, Safety Surveillance, Phillip Morris International	17.30 Development RMPs (dRMP): importance in clinical programmes Claudia Pierleoni , Director, Global Safety Surveillance, LEO Pharma	17.30 Signal detection for orphan diseases Alexandru Barbarosie , EU/UK QPPV, Global Safety Lead, Amryt Pharma	17.30 Speaker presentation	17.30 Key performance indicators in a robust global PV system Tsambika Fuchs , Team Lead PV Intelligence and Performance Management, Merck	17.30 Speaker presentation	17.30 Finding common ground for combination products regarding vigilance Ronald Boumans , Independent Medical Device Expert	17.30 Management of local PV regulation for global patient safety perspectives Antonella Fretta , Senior Director, Aggregate Reporting Team Lead, Pfizer & Laura Pasetti , Director, Aggregate Reporting Author, Pfizer	17.30 Speaker presentation	17.30 Speaker presentation

17.50 Close of conference and drinks reception

Day 2 – Thursday 10th October 2024

08.35 Chair's remarks

Morning Plenary

08.40 Keynote presentation

Patrick Caubel, Chief Safety Officer, Pfizer

09.00 Diamond Sponsor



09.20 Keynote presentation

Martine Zimmermann, Senior Vice President, Head of Regulatory, R&D Quality, Ipsen

09.40 Diamond sponsor



10.00 Diamond sponsor



10.20 Chief Safety Officer Panel Discussion

Moderator: Ira Solomon, Chief Safety Officer, Innovation, Johnson & Johnson

Fatima Bhayat, Chief Safety Officer, Head of Global Patient Safety, Amgen

Ercem Atillasoy, Chief Regulatory and Safety Officer, Jazz Pharmaceuticals

Karsten Lollike, Corporate Vice President, QPPV, Novo Nordisk

Fabian Heisig, Senior Vice President, Head Global Drug Safety & QPPV, Grunenthal Group

Avinash Kakade, Senior Vice President, Global Head of Pharmacovigilance, Dr Reddy's Laboratories

11.00 Morning Break & Poster Sessions

Track 1	Track 2	Track 3	Track 4	Track 5	Track 6	Track 7	Track 8	Track 9	Track 10
AI + AUTOMATION	RISK MANAGEMENT	SIGNAL DETECTION & MANAGEMENT	QUALITY ASSURANCE	COMPLIANCE	CASE PROCESSING	MEDICAL DEVICES	PATIENT CENTRICITY	DIGITAL TRANSFORMATION	PV OUTSOURCING
11.40 Chair: Pav Rishiraj, Director, Head of Patient Safety, Ipsen & ABPI PV Expert Chair	11.40 Chair: Frédérique Delannois, Executive Director, Safety Evaluation & Risk Management Head, Global Safety, GSK	11.40 Chair:	11.40 Chair: Vivienne van de Walle, Medical Director, PT&R	11.40 Chair: Daniela Di Cosmo, Senior Safety Advisor, Global Safety, Ferring	11.40 Chair:	11.40 Chair:	11.40 Chair:	11.40 Chair:	11.40 Chair:
11.45 AI application and automation of a probabilistic tool to assess causality Fabio De Gregorio, Vice President, Head of Drug Safety Europe, Shionogi BV	11.45 Differing periodic reports and risk management plans for regulators Bert Van Leeuwen, Senior Director, Deputy QPPV, Astellas	11.45 The role of AI in global signal detection Peter Hjelmström, Director, Uppsala Monitoring Center	11.45 Comparing and contrasting different types of PV audits Ranjana Khanna, Global Director, GVP, QA, R&D Quality, BeiGene	11.45 North American pharmacovigilance compliance requirements and inspection readiness Jaylaxmi Nalawade, Director, Pharmacovigilance and REMS, Lupin Inc	11.45 Speaker presentation	11.45 Medical safety R&D Richard Mayer, Senior Principal Engineer, Head of Medical Safety R&D, Johnson & Johnson	11.45 Title TBC Ercem Atillasoy, Chief Regulatory and Safety Officer, Jazz Pharmaceuticals & Ilaria Grisoni, Executive Director, Head of EU & International Pharmacovigilance, QPPV Office and EEA QPPV, Jazz Pharmaceuticals	11.45 The patient drug safety paradigm in the 2030's Fabio Lievano, Vice President, Safety Science, AbbVie	11.45 Speaker presentation
12.05 Sponsor presentation 	12.05 Sponsor presentation	12.05 Sponsor presentation	12.05 Sponsor presentation	12.05 Sponsor presentation	12.05 Sponsor presentation	12.05 Sponsor presentation	12.05 Sponsor presentation	12.05 Sponsor presentation	12.05 Sponsor presentation
12.25 Speaker presentation INSIFE PHARMA SPEAKER	12.25 Integrating patient insights into benefit risk assessments Suzanne Foncin, Senior Director, Head of Safety Analysis and Writing, UCB	12.25 Safety management in cell and gene therapies Asif Mahmood, Vice President, Medical Safety & Pharmacovigilance, AskBio	12.25 The realms of audits and inspections Erika Barbarosie, Associate Director, Compliance, Gilead Sciences	12.25 PSMF innovations: using digital tools to build user friendly documents Maria-Jose Reneses, Director, Deputy EU QPPV and Head of PSMF, Takeda	12.25 Speaker presentation	12.25 New standards for clinical evaluations of medical devices: upcoming ISO standards Milos Stojkovic, Safety Process Director, Roche	12.25 Monitoring patients in advance therapeutics David Chonzi, Independent PV Expert	12.25 Open access platform to advance perinatal therapeutics Adeniyi Olagunju, Tenure Track Fellow, Department of Pharmacology & Therapeutics, University of Liverpool	12.25 Speaker presentation
12.45 Sponsor presentation 	12.45 Sponsor presentation 	12.45 Sponsor presentation 	12.45 Sponsor presentation	12.45 Sponsor presentation	12.45 Sponsor presentation	12.45 Sponsor presentation	12.45 Sponsor presentation	12.45 Sponsor presentation	12.45 Sponsor presentation

13.05 Future innovations with AI: beyond back-end tools Rishi Chopra , Executive Director, Global Head of Pharmacovigilance Regions, CSL	13.05 Effectiveness of risk minimization measures in Europe Maha Elluri , Global Safety Director, EU QPPV, Indivior Pharma	13.05 Evaluation of adverse events from the Moderna COVID vaccine Priyadarshani Dharia , Director, Global Safety Epidemiology, Real World Evidence, Moderna	13.05 Inspection in gene therapies: different approaches and experiences Elisabetta Di Martino , Director, GCP, GVP & GLP, Quality Assurance, Orchard Therapeutics	13.05 Building PV and regulatory structures in a small biotech to manage inspections Darius-Jean Namdjou Global Head of Regulatory Affairs & Pharmacovigilance, Immunic Therapeutic	13.05 Optimizing case management for SMEs Kieran O'Donnell , Independent PV Expert	13.05 Speaker presentation	13.05 Towards a patient-centric shift: reinventing adherence in tuberculosis care Nibedita Rath , Scientific Director, Open Source Pharma Foundation	13.05 The promise and challenges of tokenization in clinical trial linkage to real world data Alex Liede , Senior Director, Global Epidemiology, AbbVie	13.05 Speaker presentation
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13.25 Lunch

14.25 Interactive Panels

AI & Automation Panel 1 –

Risk Management Panel 2 – QPPV Oversight for risk management planning and execution

Moderator: Ilaria Grisoni, Executive Director, Head of EU & International Pharmacovigilance, QPPV Office and EEA QPPV, **Jazz Pharmaceuticals**

Valentina Mancini, Senior Director, Pharmacovigilance, EU & UK QPPV, **Shionogi Europe & TransCelerate & Laura Paolo Boga**, Senior Director, Head of Global Pharmacovigilance, UK & EU QPPV, **Dompe Farmaceutici & Nawal Jebbar**, Lead, Safety and Pharmacovigilance, EMEA & EU QPPV, **Amylyx Pharmaceuticals**

Signal Detection & Management Panel 3 – Integration of real-world data into signal detection activities

Moderator: Akhilesh Chamediya, Global Medical Director, Patient Safety Lead, **Alexion & AstraZeneca**

Justyna Amelio, Director, Global Epidemiology, **AbbVie**

Quality Assurance Panel 4 – Enhancing cross-departmental collaboration for non-interventional studies

Moderator: Gemma Sayers, Director, Pharmacovigilance Quality Management Lead, **Regeneron**

Jin Vermaat, Vice President, Head PV Affiliate Relations, **Takeda**

Compliance Panel 5 – Optimizing PSMFs for inspection findings

Moderator: Monika Manske, Associate Director, Lead Quality Management and Deputy EEA QPPV, **Viatis**

Reserved Panel 6 -

Risk Management Panel 7 – Continuous professional training for medicine related stakeholders and patients

Moderator: Karine Palin, Eu2P Programme Manager, **University of Bordeaux**

Patient Centricity Panel 8 – What is the impact of shared decision making in patient centricity?


Moderator: Mary Lynne Van Poelgeest-Pomfret, President, **World Federation for Incontinence and Pelvic Problems (WFIPP)**

Ludovic Apoux, Director, Global Lead, Signal Detection, **Haleon UK & Shaantanu Donde**, Senior Medical Director, Head of Portfolio Management Team, Clinical Development & Medical Affairs, **Viatis**

Reserved Panel 9 -

PV Outsourcing Panel 10 – Evolution of outsourcing: highlights and challenges for vendor management

Moderator: Katherine Roberts, Vice President, Global Pharmacovigilance, **Incyte**

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15.10 Chair: 15.15 Advancing AI for PV professionals Julia Appelskog , Senior Director, EU QPPV, Head of QPPV Office, Global Vaccine Safety, Novavax	15.10 Chair: 15.15 Harmonizing local activities to improve PV efficiency Marjan Dzeperoski , RA & PV Manager, Bionika Pharmaceuticals	15.10 Chair: 15.15 Speaker presentation	15.10 Chair: 15.15 Local and regional divestment: PV collaboration and quality assurance for database transfers Lynne Comiskey , PV Regions Divestment Coordination Lead, Sanofi	15.10 Chair: 15.15 Fostering end to end collaboration between regulatory and safety organisations for RSI Jenny Griffiths , Senior Principal Associate, Medicines Quality Organisation, Eli Lilly & Co	15.10 Chair: 15.15 Speaker presentation	15.10 Chair: 15.15 Speaker presentation	15.10 Chair: 15.15 Sharing is caring – how sharing safety science insights helps affiliate PV teams realize the PV value proposition Vivien Stettner , International PV Operational Excellence Lead, AbbVie	15.10 Chair: 15.15 MHRA; a digital transformation journey Speaker TBC	15.10 Chair: 15.15 Speaker presentation
15.35 Sponsor presentation 	15.35 Sponsor presentation	15.35 Sponsor presentation	15.35 Sponsor presentation	15.35 Sponsor presentation	15.35 Sponsor presentation	15.35 Sponsor presentation	15.35 Sponsor presentation	15.35 Sponsor presentation	15.35 Sponsor presentation
15.55 Application of machine translations (MT) and AI technologies in end-to-end case processing Achilleas Kalogirou , Lead, Office of Safety Operations, AbbVie	15.55 Procedure and RMP governance: challenges and solutions for the PV sector Asa Mattsson , Senior Director, Patient Safety Risk Management, Process & Implementation, AstraZeneca & Kristin Knalstad , Director, Risk Management, Patient Safety, AstraZeneca	15.55 Speaker presentation	15.55 The role of drug safety in due diligences Giovanni Furlan , Director, Worldwide Safety Site Lead, Pfizer	15.55 Harmonising PSSFs and fulfilling requirements of local agencies Monika Zych , Director, Pharmacovigilance ECE-MEA, Baxter Corp	15.55 Speaker presentation	15.55 Speaker presentation	15.55 Real world evidence within reverse translation Jost Leemhuis , Safety Science Partner and Global Business Lead, Roche	15.55 Digital transformation: small steps versus giant leaps Andrew Moore , Director, PV Operations and Compliance, Takeda	15.55 Speaker presentation

16.15 Networking Break

<u>AI + AUTOMATION</u>	<u>RISK MANAGEMENT</u>	<u>SIGNAL DETECTION & MANAGEMENT</u>	<u>QUALITY ASSURANCE</u>	<u>COMPLIANCE</u>	<u>CASE PROCESSING</u>	<u>MEDICAL DEVICES</u>	<u>PATIENT CENTRICITY</u>	<u>DIGITAL TRANSFORMATION</u>	<u>PV OUTSOURCING</u>
16.45 Chair:	16.45 Chair:	16.45 Chair:	16.45 Chair:	16.45 Chair:	16.45 Chair:	16.45 Chair:	16.45 Chair:	16.45 Chair:	16.45 Chair:
16.50 Speaker presentation	16.50 Common platforms for education materials in differing geographies Cristina Hentea, Director, Safety Surveillance and Risk Management, Viartis	16.50 Speaker presentation	16.50 Speaker presentation	16.50 Compliance documentation – does it have to be complicated? Carrie Scott, Head of Global PV Compliance and Policy, AbbVie	16.50 Speaker presentation	16.50 Speaker presentation	16.50 Speaker presentation	16.50 Speaker presentation	16.50 Speaker presentation
17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation	17.10 Sponsor presentation
17.30 Speaker presentation	17.30 Contraception in clinical trials Kishore Saha, Chief Specialist, Lundbeck	17.30 Speaker presentation	17.30 Speaker presentation	17.30 Speaker presentation	17.30 Speaker presentation	17.30 Speaker presentation	17.30 Speaker presentation	17.30 Speaker presentation	17.30 Speaker presentation

17.50 Close of conference