World Drug Safety Europe Congress 2023

4-5th October 2023 – Amsterdam – Halls 2 & 3, Amsterdam RAI

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

1. **Patrick Caubel**, Chief Safety Officer, **Pfizer**
2. **Ira Solomon**, Chief Safety Officer, Innovation, **Johnson & Johnson**
3. **Fatima Bhayat**, Vice President, Head of Global Patient Safety and Chief Safety Officer, **Amgen**
4. **Stewart Geary,** Global Safety Officer, **Eisai**
5. **Fabian Heisig,** Senior Vice President, Head Global Drug Safety & Qualified Person for Pharmacovigilance, **Grunenthal Group**
6. **Phil Tregunno,** Deputy Director, Patient Safety Monitoring, **Medicines & Healthcare Products Regulatory Agency**
7. **Michael von Forstner,** Global Head of Clinical Safety and Pharmacovigilance, Biosimilars, **Biogen**
8. **Karsten Lollike**, Corporate Vice President and QPPV, **Novo Nordisk**
9. **Uwe Gudat**, Chief Medical Officer, **Aretaeus sarl**
10. **Shaloo Pandhi**, Senior Vice President, Global Head, Patient Safety, **Sandoz**
11. **Fabio De Gregorio**, Vice President, Head of Drug Safety Europe, **Shionogi BV**
12. **Claudia Lehmann**, Vice President, Head, Global Pharmacovigilance Operations & Systems, **Boehringer Ingelheim**
13. **Francoise Sillan**, Vice President, Global Patient Safety, EU & UK QPPV, **Ipsen**
14. **Jeremy Jokinen,** Vice President, Global Risk Management & International Patient Safety, **Bristol Myers Squibb**
15. **Pilar Carrero**, Vice President, Global Safety, **LEO Pharma**
16. **Wasim Anwar**, Vice President & Deputy QPPV, Global Safety, **Novo Nordisk**
17. **Lisa Benaise**, Vice President, Head of Pharmacovigilance, **Calliditas**
18. **Gloria Bustos,** Senior Director, Head of Pharmacovigilance, EMEA & APAC / Global Patient Safety**, Baxter Healthcare**
19. **Emmanuelle Pines**, Head of Safety Policy & Process Oversight, QPPV Office, **Janssen**
20. **David Chonzi**, Global Head of PVE, **Instil Bio**
21. **Deanna Montes de Oca,** Global Head of PV Case Management**, Moderna**
22. **Balaji Malla**, Head of Pharmacovigilance, EU & UK QPPV, **Dr Reddy's Laboratories**
23. **Sarah Vaughan**, Head of Vigilance Development, **MHRA**
24. **Luiz Lima**, Vice President, Global Patient Safety, Therapeutic Area Lead, Neuroscience, **Ipsen**
25. **Linda Harmark**, Deputy Director, **Netherlands Pharmacovigilance Centre Lareb**
26. **Wally Landsberg**, Vice President, Global Head Medical Safety, **Kyowa Kirin**
27. **Pav Rishiraj**, Director, Head of Patient Safety, **Ipsen** & **ABPI** PV Expert Chair
28. **Deepa Venkataraman**, Vice President, Drug Safety and Pharmacovigilance, **Corcept Therapeutics**
29. **Jin Vermaat**, Vice President, Head PV Affiliate Relations, **Takeda**
30. **Jefferson Guillon**, Head of Outsourced Managed Services, **CSL Behring**
31. **Tuula Ikonen**, Head of Pharmacovigilance Department, **European Organisation for Research and Treatment of Cancer (EORTC)**
32. **Howard Snow**, Vice President, Head of Pharmacovigilance, **SOBI**
33. **Laura Paolo Boga,** Head of Global Pharmacovigilance, UK & EU QPPV, **Dompe Farmaceutici SPA**
34. **Mason Shih**, Vice President, Safety Science, **Biomarin**
35. **Santanu Mukhopadhy**, Head, Medical Safety, **VecturaFertin Pharma**
36. **Mette Stie Kallesoe**, Head of Pharmacovigilance, QPPV, **Hansa Biopharma**
37. **Olaf Schickling**, Senior Director, EEA QPPV, **BeiGene**
38. **Balwant Heer**, Vice President, Global Head of Drug Safety, **Viatris**
39. **Juan Daccach**, Vice President, Global Product Safety, **Merz Aesthetics**

40. **Israel Gutierrez**, Vice President, Drug Safety & Pharmacovigilance, **Compugen**

41. **Dagmara Okla**, Senior Director, Head of Global Safety, Clinical Development & Medical Affairs Quality, Excellence & Governance, EU QPPV, **Haleon**

42. **Devi Padmanaban**, Executive Director, Drug Safety, **Neurocrine Biosciences**

43. **Rainer Heissing**, Executive Director, Deputy EU/UK QPPV, **Gilead Science**

44. **Jolanda De Bruijne**, Executive Director, PV Compliance, Oversight & Process Excellence (COPE), Pharmacovigilance Operations, **Astellas**

45. **Klaudija Marijanovic Barac**, Senior Director, Global Patient Safety & PV – TPC, Deputy EU & UK QPPV, **Teva Pharmaceuticals**

46. **Kapil Bhutada**, Senior Director, Quality and Compliance, **Inozyme Pharma**

47. **Julia Appelskog**, EU QPPV, Global Vaccine Safety, **Novavax**

48. **Valentina Mancini**, Senior Director, Pharmacovigilance, QPPV, **Shionogi Europe & TransCelerate**

49. **Marcin Kruk**, Senior Director, Drug Safety Unit Regional Head, Europe, Africa & Middle East, **Pfizer**

50. **Marcin Marciniak**, Senior Director, Global Safety and PV Expert WHC, **Gedeon Richter**

51. **Attila Olah**, Head, Global Patient Safety, EU & UK QPPV, **Gedeon Richter**

52. **Dnyaneshwar Sanap**, EU & UK QPPV, Head, Regional PV and Global Compliance Training, **Glenmark Pharmaceuticals**

53. **Ellen Bonagua**, Executive Director, Drug Safety and Pharmacovigilance, **Insmed Incorporated**

54. **Lucy Hampshire**, Associate Vice President, Head, Medicines Quality Organisation International, **Eli Lilly & Co**

55. **Steve Dingman**, Vice President, Head of Pharmacovigilance, **Immunogen**

56. **Heinrich Martens**, Vice President, Regulatory Affairs, MedTech, **Fresenius Kabi**

57. **Richard Dart**, Executive Director, **Rocky Mountain Poison & Drug Safety**

58. **Raj Bhogal**, Senior Director, R&D Business Strategy & Operations, **Jazz Pharmaceuticals**

59. **Antonia Coppin-Renz**, Senior Director, TA Lead Digital Therapeutics & Deputy Global, EU and UK QPPV, **Otsuka**

60. **Klaus Bitsch-Jensen,** Director, Head of QPPV Office, EU QPPV, **ALK**

61. **Tanja Fahlbusch**, Deputy Head, International Pharmacovigilance Business Process Management, **Roche**

62. **Mattia Calissano,** Head of Pharmacovigilance**, Orchard Therapeutics**

63. **Ellen Ravn Englev**, Senior Director, Case Mgmt. & PV system support, Safety Operations, Global Safety, **Novo Nordisk**

64. **Sean Burke**, Senior Director, Regional Lead, International Pharmacovigilance, **MSD**

65. **Nicola Wallis**, Executive Director, PV Innovation, UK QPPV, **Beigene**

66. **Veronica Urdaneta**, Senior Director, Global Safety Physician, Pharmacovigilance, **Moderna**

67. **Franciane Flament**, Senior Director, GPS Regional Oversight Team Head, **Ipsen**

68. **Shabana Dange**, Senior Director, Global Safety Lead, **Argenx**

69. **Suzanne Foncin**, Senior Director, Head of Safety Analysis and Writing, **UCB**

70. **Alina Tudor,** Senior Director, Pharmacovigilance, **Kyowa Kirin International**

71. **Veronica Fjellstrom**, Head, Global Patient Safety & Medical Information, EU & UK QPPV, **Karo Pharma AB**

72. **Myriam Salem**, Pharmacovigilance Manager, **Health Canada**

73. **Philip Jones**, Senior Director, Disease Area Cluster Lead, Inflammation & Immunology, **Pfizer**

74. **Raphael Van Eemeren**, Senior Director, EU/UK QPPV, Global Patient Safety, **Amgen**

75. **Antonella Fretta**, Senior Director, Aggregate Reporting Team Lead, **Pfizer**

76. **Sunita Dhar**, Executive Medical Group Director, Clinical Safety, **Genentech**

77. **Sameen Desai**, Executive Director, Head of Worldwide Patient Safety and Risk Management IT, **Bristol Myers Squibb**

78. **Marianne Soergel-Ahovi**, Drug Safety Lead, **Molecular Partners**

79. **Amina Baljic**, Head of PV Ops & PV Excellence, **Grunenthal Group**

80. **Stephanie Tcherny-Lessenot,** Head of Benefit-Risk Evaluation, **Sanofi**
81. **Kate Anteyi**, Director, Global Safety Physician, **Moderna**
82. **Marjan Dzeparoski**, RA & PV Manager, **Bionika Pharmaceuticals**
83. **Olga Menang**, Director, Drug Safety and Pharmacovigilance, **Fresenius Kabi SwissBioSim**
84. **Judy Barretto**, Global Process Owner, Signal Management Director, **Roche**
85. **Ranga Reddy,** Director, Global Head of Drug Safety Technologies, **CSL Vifor**
86. **Roger Mutter**, Deputy QPPV, **Galapagos NV**
87. **Fabrice Besle**, Director, PV Database & Analytic Reporting, **Ipsen**
88. **Vipin Sethi**, Head of Global Pharmacovigilance and Medical Affairs, **Cadila Pharma**
89. **Jorgen Matz**, Head of Global Pharmacovigilance & Clinical Quality, EU QPPV, **Insud Pharma**
90. **David Lilienfeld**, Vice President, Drug Safety and Pharmacovigilance, **Elevar Therapeutics**
91. **Jan Cleerbout**, Deputy EU QPPV, QPPV Office, **Janssen**
92. **Katarzyna Gruchala**, Director, PV Operations Case Processing, **Moderna**
93. **James Whitehead**, Senior Director, Devices & Digital Safety, **AstraZeneca**
94. **Darren Stewart**, Chief Experience Officer, Competency Accelerator, **Roche**
95. **Phillip Eichorn**, Global Head of Drug Safety, **Amryt Pharma**
96. **Ram Vempati**, Former Head of Pharmacovigilance, **Arcellx**
97. **TBC Ketan Marulkar**, Senior Director, Patient Safety, **Eli Lilly & Co**
98. **Inge Jeding-Jansen**, Senior Director, Head of Global Pharmacovigilance, **ALK**
99. **Majken Berghuis**, Director, Pharmacovigilance, International Operations, **Novo Nordisk**
100. **James Eldridge**, Director, Pharmacovigilance North America, **Y-mAbs**
101. **Henk Johan Streefkerk**, CEO & Medical Director, **Amarna Therapeutics**
102. **Peter De Veene**, QPPV, **Incyte**
103. **Karolina Danysz**, Associate Director, PV Affiliate Relations Liason, EUCAN, **Takeda**
104. **Maha Elluri**, Global Safety Director, **Indivior Pharma**
105. **Gemma Sayers**, Director, Pharmacovigilance Quality Management Lead, **Regeneron Pharma**
106. **Monika Kowalska**, Director, PV Operations ICSR Quality, **Moderna**
107. **Reinhold Schilling**, Head of Global Pharmacovigilance, EU QPPV, **Worwag Pharma**
108. **Samah Ragab**, Director, Regulatory Affairs & PV, Middle East, **Organon**
109. **Gemma Jimenez Sese**, Director, Patient Safety, **Almirall**
110. **Marina Suvakov**, Global Head Product Safety Surveillance, **Phillip Morris International**
111. **Siva Kumar Buddha,** Global Pharmacovigilance Physician, Senior Manager, **Teva Pharmaceuticals**
112. **Markus Drumm**, Head of Global Patient Safety Regions, **Merck**
113. **Wumi McDowall**, Director, Pharmacovigilance, Medical and Regulatory QA, **Seqirus**
114. **Ricarda Tiemeyer**, Head of Pharmacovigilance, DACH Region, **Biogen**
115. **Linda Bech**, Associate Director, Head of Patient Safety Nordics, **Gilead Sciences**
116. **Ajibade Adesina**, Director, PV Process Excellence and Learning Strategy, **Bristol Myers Squibb**
117. **Erika Barbarosie**, Associate Director, Compliance, **Gilead Sciences**
118. **Manal Younus**, Advisory Board Member, Patient Engagement Co Lead, **ISoP**
119. **Mary Lynne Van Poelgeest-Pomfret**, President, **World Federation for Incontinence and Pelvic Pain (WFIPP)**

120. **Karin Thelen**, Head of Drug Safety, **Cardior Pharmaceuticals**
121. **Giovanni Furlan**, Worldwide Safety Site Lead & Safety Risk Lead Director, **Pfizer**
122. **Monika Manske,** Lead Quality Management and Deputy EEA QPPV**, Viatris**
123. **Bert Van Leeuwen**, Deputy QPPV, **Astellas**
124. **Anne Raison**, Head of Quality and Medical Compliance Management, **Roche**
125. **Lilliam Fernandes**, Director, Clinical Safety and Pharmacovigilance, **Adaptimmune**
126. **Michael Becker**, International PV, Global Head, PV Hubs, **Roche**
127. **Kishore Saha**, Chief Specialist, **Lundbeck**
128. **Jost Leemhuis**, Safety Science Partner and Global Business Lead, **Roche**
129. **Santiago Schiaffino**, Medical Director, Senior Patient Safety Physician, **Astra Zeneca**
130. **Lynne Comiskey,** QPPV Compliance and Program Manager, **Sanofi**
131. **Maria Dahlin**, Director, Global Pharmacovigilance & Patient Safety, **Sobi**
132. **Robert Massouh**, Head, Risk Management and Benefit-Risk Evaluation**, GSK**
133. **Sophie Radicke**, Head of GPvP and Senior Pharmacovigilance Inspector, **MHRA**
134. **Robert Di Giovanni**, Global Patient Safety Lead, **Novartis**
135. **Maria Tello**, Senior Medical Director, Patient Safety & PV Lead, Strategy and Innovation, **Horizon Therapeutics**
136. **Ariane Stollenwerk**, Head of Central Europe & Asian Int. Markets, International PhV, **UCB**
137. **Caitlin Keel**, Director, Global Head of Case Management & Standards, Global Product Safety and Pharmacovigilance, **United Therapeutics**
138. **John Poustie**, EMEA Pharmacovigilance Director, UK QPPV, **Haleon**
139. **Elian Khazneh**, Head of GPS, Benefit Risk Strategy and Management, Global Patient Safety, **Merck**
140. **Jaylaxmi Nalawade**, Associate Director, Pharmacovigilance and REMS, **Lupin Inc**
141. **Jill Leake**, Director, Head of Clinical Safety Operations, **Merck**
142. **Paridhi Anand**, Director, PV Operations, Standard and Training in Case Processing, **Moderna**
143. **Emma Boulton**, Director, Safety Operations, **Mundipharma**
144. **Marianne Mounir,** Senior Global System Auditor, **Bayer**
145. **Mircea Ciuca**, Independent PV Expert
146. **John Solomon,** Head of Pharmacovigilance, UK and Ireland, **Sanofi**
147. **Margherita D'Antuono** EU-UK QPPV, **Piramal Critical Care**
148. **Wivina De Waele**, Senior Director, Safety Lead Europe, Global Patient Safety **Alexion**
149. **Irina Maria Ciubotaru**, Head of Global Pharmacovigilance and Drug Safety, **ITM Isotopen Technologien Munchen**
150. **Ranjana Khanna,** Director, Head of PV Quality Assurance**, Nestle Health Sciences**
151. **Monika Zych**, Director, Pharmacovigilance ECEMEA, **Baxter Corp**
152. **Jutta Syha**, Independent PV Expert
153. **Maria-Jose Reneses**, Director, Deputy EU QPPV and Head of PSMF, **Takeda**
154. **Leith Kwaan**, QPPV, **National Bioproducts Institute**
155. **Kieran O'Donnell**, Independent PV Expert
156. **Sutirtha Mukhopadhyay**, Senior Patient Safety Physician, **Boehringer Ingelheim**
157. **Mijal Chavda**, Senior Director, Global Head of GxP Inspections & GVP Quality, **Kyowa Kirin**
158. **Akhilesh Chamediya**, Director, Senior Medical Expert, EU QPPV, **AiCuris**
159. **Joann Evangelista,** Director, Head of PV Operations, US Patient Safety, **Genentech &**

160. **Mina G Awad,** Pharmacovigilance Senior Manager and QPPV, Middle East, **Kyowa Kirin International**
161. **Jessica Marlind Wurtele**, Director, Patient Safety Excellence, **AstraZeneca**
162. **Gabrielle Amselem**, Director, Patient Safety Excellence, **Alexion, AstraZeneca Rare Disease**
163. **Natasa Mihajlovic**, Managing Director, **NostraPharma Ltd**
164. **Simon Ashworth**, Head of Pharmacovigilance and Medical Safety, **Ono Pharmaceuticals**
165. **Sergiy Kryvych**, Senior Drug Safety Officer & Medical Advisor, Deputy Local Pharmacovigilance Responsible Person, **Pfizer**
166. **Jeremie Dedessus Le Moutier**, Head of Global PV Excellence, Global Safety, **GSK**
167. **Milos Stojkovic**, Safety Process Director, **Roche**
168. **Emma Wiman**, Director, Regulatory Compliance & Quality, EMENA, **Accord Healthcare**
169. **Anna Pelnikevich**, Director, Head, Project Management and Periodic Safety Reports, **Merck**
170. **Natalie Farrar**, Director, Safety and Pharmacovigilance, **ViiV Healthcare**
171. **Amit Kubavat**, Global Program Safety Lead, **Sandoz**
172. **Teresa Saragoca**, Director, Regulatory Affairs & Technical Manager, **ITALFARMACO**
173. **Sandra Reda**, Quality Assurance Specialist & Deputy QPPV, **RAY-CRO**
174. **Sarah Al-Musaed**, Regulatory Affairs and Drug Safety Manager (LRP-PV), **Grunenthal Group**
175. **Anja-Helena Loos**, Director, Biostatistics Oncology, **Merck**
176. **Joan D'Souza**, Independent PV Expert
177. **Sibel Guerler**, Head of Innovation, Partnerships and Process Optimisation, WorldWide Patient Safety, **Bristol Myers Squibb**
178. **Ibrahim Altamawy**, Medical Affairs & Compliance Regional Head (MENA), **SAJA Pharmaceuticals**
179. **Donia Al-Bastaky**, Head of Drug Safety, **Kuwait Health Authority**
180. **George P. Patrinos**, Professor, Department of Pharmacy, **University of Patras** & Adjunct Professor, Department of Genetics and Genomics, **United Arab Emirates University**
181. **Marco Colombati**, PV Operations Manager, **ITALFARMACO SPA**
182. **Tommaso Venturi**, Corporate Pharmacovigilance Risk Assessment Specialist, **ITALFARMACO SPA**
183. **Janni Hermansen**, Head, Global Safety Surveillance, Biologics & Devices, **Leo Pharma**
184. **Hans-Jörg Römming,** Head, Global Patient Safety Operations, **Merck Healthcare KGaA**
185. **Anna Karin Traff**, Director, ICSR Lead, **AstraZeneca**
186. **Galyna Cordero**, QPPV, Head of Pharmacovigilance Department, **JSC Farmak**
187. **Ana Sofia Afonso**, Director, Pharmacoepidemiology, Global Patient Safety, **Eli Lilly**
188. **Anna Liptak Askne**, Director, ICSR Post-Marketing, **AstraZeneca**
189. **Tea Babic**, Director, Head of PV Audits and Inspections, Deputy Head PV Compliance, **Teva Pharmaceuticals**
190. **Daniela Di Cosmo**, Senior Safety Advisor, Global Safety, **Ferring**
191. **Daniela Gramaglia**, Medical Device Vigilance Manager, **Chiesi**
192. **Eva van Engelen,** Director, Patient Safety**, Gilead Sciences**
193. **Branka Stojanovic**, Country Safety Lead, Serbia, QPPV, **Pfizer**
194. **Franziska Rathjens**, Head of Business Process Management & PV Tools, Deputy QPPV, **B Braun**
195. **Rudi Scheerlinck**, Safety Strategy Lead, **Merck Healthcare Oncology**
196. **Maria Maddalena Lino**, Safety Risk Lead Director, COVID Vaccine, **Pfizer**
197. **Petra Lerner-Hiller**, PV Quality and QPPV Relations Lead, Deputy QPPV, **Merck**
198. **Charlotte van Haverbeke,** Director, Global Safety, Clinical Development & Medical Affairs (GSM), Process Excellence **Haleon**
199. **Leko Mdladla**, Clinical Safety Manager, **ViiV Healthcare**

200. **Conny Johansson**, Alliance Management Lead, **Roche**
201. **Thomas Organ**, Safety Science Director, Neuroscience, Global Patient Safety, **Ipsen**
202. **Marco Tuccori**, Pharmacovigilance Manager, **University Hospital of Pisa &** Coordinator, **Tuscan Regional Centre of Pharmacovigilance &** Co-Chair, **ISoP Scientific Board**
203. **Melanie Dullemond**, Compliance Head, Medical and PV Quality, **Sanofi**
204. **Begum Benli Peker**, Director, Head of Patient Safety Netherlands & Hub Lead, **Bristol Myers Squibb**
205. **Marko Strott**, Associate Director, Partnership Management, Global Patient Safety, **Merck**
206. **Olga Panek-Bialkowska,** Associate Director, Global Pharmacovigilance Case Management, **MSD**
207. **Isabella Caramuta**, Deputy QPPV, Pharmacovigilance Manager, **Shionogi Europe**
208. **Lionel Van Holle**, Founder, **OpenSourcePV**
209. **Marlo Corrao**, Quality Director, Pharmacovigilance Excellence, **GSK**
210. **Diane Halle**, Senior Manager, Pharmacovigilance Quality Assurance, **Alnylam Pharmaceuticals**
211. **Melanie Demarke**, Director, Global Process Owner, PV Excellence, Global Safety, **GSK**
212. **Juergen Dietrich**, Senior Lead Data Scientist, Pharmacovigilance, **Bayer**
213. **Carolyn Cranfield**, Director, Global Process Owner, PV Excellence, Global Safety, **GSK**
214. **Abiola David**, Director, Medical Information, Safety Services & Vendor Management, **GSK**
215. **Nadezda Abramova**, Safety Strategy Lead, **Merck**
216. **Leesha Balramsingh-Harry**, Safety Data Acquisition Lead, **Merck**
217. **Ilana Frishman**, Safety Director, **Pluri**
218. **Alaa Badran**, Quality Assurance Specialist, **RAY CRO**
219. **Nibedita Rath**, Scientific Director, **Open Source Pharma Foundation**
220. **Clara Goncalves**, Head, QPPV & Alliance Office, **Grunenthal Group**
221. **Delphine Bertram**, Head, Safety Vigilance, EMEA Operations, EU QPPV, **Santen**
222. **Hadir Rostom**, President, **ISoP Egypt Chapter** and Lecturer, Faculty of Pharmacy, **Modern Sciences and Arts Univefrsity**
223. **Azira Cajic,** Head of Division for Pharmacovigilance and Materiovigilance, PV Inspector, **Agency for Medicinal Product and Medical Devices, Bosnia**
224. **Tsambika Fuchs**, Team Lead, PV Intelligence and Performance Management, **Merck**
225. **Meredith Kiley**, Senior PV Operations Manager, US Patient Safety, **Genentech**
226. **Gemma Berry Jones**, Associate Director, GVP Quality, **Kyowa Kirin**
227. **Dimitris Zampatis**, Global Program Safety Lead, Global Patient Safety, **Sandoz**
228. **Bartosz Olas**, Principal Safety Data Manager, Global Pharmacovigilance Case Management, **MSD**
229. **Kavita Ramji**, Safety Officer, Quality Manager, **Pfizer**
230. **Heinz Weidenthaler**, Vaccine Pharmacovigilance Expert
231. **Nathan Rivers**, Senior Manager, Medical Safety, **Jazz Pharmaceuticals**
232. **Garry Flounders**, Global Pharmacovigilance Operations Lead, Biosimilars, **Biogen**
233. **Mark Widdowson**, Manager, Innovation, **Bristol Myers Squibb**
234. **Patricia Harding**, Senior Advisor, Medicines Quality Organisation, **Eli Lilly & Co**
235. **Maud Le Petitcorps**, Associate Director, Safety Oversight, **Johnson & Johnson**
236. **Iva Zgombic Rukavina**, Medical Affairs and Pharmacovigilance Senior Associate, **Belupo**
237. **Smruti Kothari**, Associate Director, PV Quality Operations, **Alexion, AstraZeneca Rare Disease**
238. **Meenakshi Ramachandran**, Manager, Drug Safety, **Molecular Partners**

Day 1 – Wednesday 4th October 2023

08.55 **Chair's remarks**
Karsten Lollike, Corporate Vice President and QPPV, **Novo Nordisk**

Morning Plenary

09.00 **Key considerations for how to effectively manage the safety oversight of cross-sector combination product solutions**
Ira Solomon, Chief Safety Officer, Innovation, **Johnson & Johnson**

09.20 **The transformative safety platform that puts the patient at the center for an integrated patient experience**
Beena Wood, Senior Vice President, Safety & Medical Affairs Product Management, **ArisGlobal**

09.40 **Complexities and gaps in digital transformation**
Shaloo Pandhi, Senior Vice President, Global Head, Patient Safety, **Sandoz**

10:00 **Large language models and generative AI: implications and opportunities for pharmacovigilance**
Bruce Palsulich, Vice President, Product Strategy, **Oracle Health Sciences**

10.20 **Panel Discussion: Digital Transformation – Innovator, disruptor or interrupter to the safety of patients?**
Moderator: Claudia Lehmann, Vice President, Head, Global Pharmacovigilance Operations & Systems, **Boehringer Ingelheim**
Phil Tregunno, Deputy Director, Patient Safety Monitoring, **Medicines & Healthcare Products Regulatory Agency**
Deepa Venkataraman, Vice President, Drug Safety and Pharmacovigilance, **Corcept Therapeutics**
Fabian Heisig, Senior Vice President, Head Global Drug Safety & Qualified Person for Pharmacovigilance, **Grunenthal Group**

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**	**DIGITAL TRANSFOR-MATION**	**REGULATORY AFFAIRS**	**VACCINE SAFETY**	**PV OUTSOURCING**
11.30 **Chair:** **Pav Rishiraj**, Director, Head of Patient Safety, **Ipsen** & **ABPI** PV Expert Chair	11.30 **Chair:** **Mette Stie Kallesoe**, Head of Pharmacovigilance, QPPV, **Hansa Biopharma**	11.30 **Chair:** **Mattia Calissano,** Head of Drug Safety and Risk Management, Italy & UK QPPV**, Orchard Therapeutics**	11.30 **Chair:** **Valentina Mancini**, Senior Director, Pharmacovigilance, QPPV, **Shionogi Europe & TransCelerate**	11.30 **Chair:** **Franciane Flament**, Senior Director, GPS Regional Oversight Team Head, **Ipsen**	11.30 **Chair:** **Begum Benli Peker**, Director, Head of Patient Safety Netherlands & Hub Lead, **Bristol Myers Squibb**	11.30 **Chair:** **INSIFE**	11.30 **Chair:** **Reinhold Schilling**, Head of Global Pharmacovigilance, EU QPPV, **Worwag Pharma**	11.30 **Chair:** **Donia Al-Bastaky**, Head of Drug Safety, **Kuwait Health Authority**	11.30 **Chair:** **Wally Landsberg**, Vice President, Global Head Medical Safety, **Kyowa Kirin**
11.35 **Automation and pharmacovigilance: identifying risk factors for AEs** **Michael von Forstner,** Global Head of Clinical Safety and Pharmacovigilance, Biosimilars, **Biogen**	11.35 **CIOMS XII: Key principles for benefit risk assessments** **Stewart Geary,** Global Safety Officer, **Eisai**	11.35 **Running DMCs from PV: pros and cons** **Karsten Lollike**, Corporate Vice President and QPPV, **Novo Nordisk**	11.35 **Auditing special programs: a fine line between GCP and GVP** **Ranjana Khanna**, Director, Head of Quality Assurance PV, **Nestle Health Sciences**	11.35 **Increasing productivity in ICSR management with automation** **Hans-Jörg Römming,** Head, Global Patient Safety Operations, **Merck Healthcare KGaA**	11.35 **Devices transforming pharmacovigilance** **James Whitehead**, Senior Director, Devices and Digital Safety, **AstraZeneca**	11.35 **INSIFE**	11.35 **Interfaces between regulatory affairs and drug safety** **Sarah Al-Musaed**, Regulatory Affairs and Drug Safety Manager (LRP-PV), **Grunenthal Group**	11.35 **Implementation of competitive safety intelligence in an early post marketing context – a case study** **Lionel Van Holle**, Founder, **OpenSourcePV**	11.35 **PV outsourcing in the MENA region** **Mina G Awad,** Pharmacovigilance Senior Manager and QPPV, Middle East, **Kyowa Kirin International**
11.55 **Applying AI earlier in pharmacovigilance workflow to optimize patient centricity** **Joann Evangelista,** Director, Head of PV Operations, US Patient Safety, **Genentech & Meredith Kiley**, Senior PV Operations Manager, US	11.55 **Platinum sponsor presentation**	11.55 **Enhancing Patient Safety: Detecting Signals to Risk Mitigation Actions,** **Kausik Maiti**, Senior Medical Director and Global Head of Safety Medical Sciences, **Parexel International**	11.55 **PRODUCT LIFE GROUP**	11.55 **Platinum sponsor presentation**	11.55 **Platinum sponsor presentation**	11.55 **INSIFE**	11.55 **Platinum sponsor presentation**	11.55 **Platinum sponsor presentation**	11.55 **Ensuring quality, when PV is outsourced** **Noelle Humphrey**, Vice President of Quality, **PrimeVigilance**

Patient Safety, **Genentech & Marie Flanagan**, Director, Offering Management, **IQVIA**									
12.15 **AI & Real-World Evidence** **Stephanie Tcherny-Lessenot,** Head of Benefit-Risk Evaluation, **Sanofi**	12.15 **RMP for biosimilars** **Dimitris Zampatis**, Global Program Safety Lead, Global Patient Safety, **Sandoz**	12.15 **Validation of signals by means of a probabilistic causality assessment tool** **Fabio De Gregorio**, Vice President, Head of Drug Safety Europe, **Shionogi BV**	12.15 **Company core safety information versus local labelling** **Delphine Bertram**, Head, Safety Vigilance, EMEA Operations, EU QPPV, **Santen**	12.15 **Case processing improvements with automation** **Deanna Montes de Oca,** Senior Director, Global PV Operations, Case Management, **Moderna**	12.15 **Combination products: processes and practicalities** **Maria Tello**, Senior Medical Director, Patient Safety & PV Lead, Strategy and Innovation, **Horizon Therapeutics**	12.15 **Data science: upskilling the PV profession** **Phillip Eichorn**, Global Head of Drug Safety, **Amryt Pharma**	12.15 **Preparing a regulatory safety response** **Nicola Wallis**, Executive Director, PV Innovation, UK QPPV, **Beigene**	12.15 **Impacts of MRNA vaccines on patient safety** **Wumi McDowall**, Director, Pharmacovigilance, Medical and Regulatory QA, **Seqirus**	12.15 **Managing PV compliance with small distribution partners** **Jutta Syha**, Independent PV Expert
12.35 **Leveraging LLMs & workflow automation for aggregate reporting** **Lalit Gehani**, Practice Lead, Reporting & Analytics, **Ultragenic**	12.35 **Proactively plan you (d)RMP: when to start?** **Hanneke Dominicus**, Senior Manager, Benefit Risk, **ProPharma Group**	12.35 **Optimizing signal detection and management within a compliance framework** **Philip Hofmann**, Director of Pharmacovigilance and Global QPPV, **Navitas Life Sciences**	12.35 **Gold sponsor presentation** **COD RESEARCH**	12.35 **Navigating and automation strategy and making the leap to AI** **Michael Braun-Boghos**, Senior Director, Safety Strategy, **Oracle Health Sciences**	12.35 **Gold sponsor presentation** **PINNAXIS**	12.35 **Gold sponsor presentation** **GENERIS**	12.35 **Gold sponsor presentation**	12.35 **Gold sponsor presentation**	12.35 **Gold sponsor presentation** **INSUVIA**
12.55 **Natural language processing in pharmacovigilance and aggregate reports** **Israel Gutierrez**, Vice President, Drug Safety & Pharmacovigilance, **Compugen**	12.55 **Risk management of newly introduced oral contraceptives** **Jorgen Matz**, Head of Global Pharmacovigilance & Clinical Quality, EU QPPV, **Insud Pharma**	12.55 **Ways to choose statistical methodologies for signal detection** **Siva Kumar Buddha,** Global Pharmacovigilance Physician, Senior Manager, **Teva Pharmaceuticals**	12.55 **Local and regional QPPV oversight integration into a global PV system** **Petra Lerner-Hiller**, PV Quality and QPPV Relations Lead, Deputy QPPV, **Merck**	12.55 **AAV based gene therapies: case processing and signal detection challenges** **Mason Shih**, Vice President, Safety Science, **Biomarin**	12.55 **Building a product safety team** **Juan Daccach**, Vice President, Global Product Safety, **Merz Aesthetics**	12.55 **Staffing needs and structure of a PV department** **Rudi Scheerlinck**, Safety Strategy Lead, **Merck Healthcare Oncology**	12.55 **Regulatory intelligence in pharmacovigilance and future readiness** **Ibrahim Altamawy**, Medical Affairs & Compliance Regional Head (MENA), **SAJA Pharmaceuticals**	12.55 **Possible biases in pharmacovigilance vaccine data during the pandemic** **Maria Maddalena Lino**, Safety Risk Lead Director, COVID Vaccine, **Pfizer**	12.55 **The world of outsourcing: recent developments and insights** **Abiola David**, Director, Medical Information, Safety Services & Vendor Management, **GSK**
13.15 Lunch									
13:15 Diamond Sponsor Workshop: Best practices for safety management in pharmacovigilance **Inder Sachdeva**, Global Delivery Leader, **Cognizant** **Venkat Venkataramanan**, PV Domain Lead, **Cognizant**									
14.15 Interactive Panels **AI & Automation Panel 1 – Processing innovations: increasing quality and efficiency using AI and automation** **Moderator: Amina Baljic**, Head of PV Ops & PV Excellence, **Grunenthal Group** **Fabrice Besle**, Director, PV Database & Analytic Reporting, **Ipsen & Shaloo Pandhi**, Senior Vice President, Global Head, Patient Safety, **Sandoz & Marcin Kruk**, Senior Director, Drug Safety Unit Regional Head, Europe, Africa & Middle East, **Pfizer & Kapil Bhutada**, Senior Director, Quality and Compliance, **Inozyme Pharma** **Risk Management Panel 2 – Evolutions in local risk minimization activities: effectiveness assessments using pharmacoepidemiology tools** **Moderator: John Solomon,** Head of Pharmacovigilance, UK and Ireland, **Sanofi** **Roger Mutter**, Deputy QPPV, **Galapagos NV & Maha Elluri**, Global Safety Director, **Indivior Pharma & Myriam Salem**, Pharmacovigilance Manager, **Health Canada & Anna Pelnikevich**, Director, Head, Project Management and Periodic Safety Reports, **Merck & Suzanne Foncin**, Senior Director, Head of Safety Analysis and Writing, **UCB** **Signal Detection & Management Panel 3 – Safety related posts to agency websites and submissions** **Moderator: Sean Burke**, Senior Director, Regional Lead, International Pharmacovigilance, **MSD** **Thomas Organ**, Safety Science Director, Neuroscience, Global Patient Safety, **Ipsen & Akhilesh Chamediya**, Director, Senior Medical Expert, EU QPPV, **AiCuris & Ana Sofia Afonso**, Director, Pharmacoepidemiology, Global Patient Safety, **Eli Lilly & Amit Kubavat**, Global Program Safety Lead, **Sandoz** **Quality Assurance & Compliance Panel 4 – Inspections from an auditor's perspective** **Moderator: Raj Bhogal**, Senior Director, R&D Business Strategy & Operations, **Jazz Pharmaceuticals** **Tea Babic**, Director, Head of PV Audits and Inspections, Deputy Head PV Compliance, **Teva Pharmaceuticals & Mijal Chavda**, Senior Director, Global Head, GxP Inspections & GVP Quality, **Kyowa Kirin & Lucy Hampshire**, Associate Vice President, Head, Medicines Quality Organisation International, **Eli Lilly & Co & Marianne Mounir**, Senior Global System Auditor, **Bayer & Lynne Comiskey,** QPPV Compliance and Program Manager, **Sanofi**									

Case Processing Panel 5 – Developing standards and approaches for quickly scaling company case processing
Moderator: Paridhi Anand, Director, PV Operations, Standard and Training in Case Processing, **Moderna**
Majken Berghuis, Director, Pharmacovigilance, International Operations, **Novo Nordisk & Inge Jeding-Jansen**, Senior Director, Head of Global Pharmacovigilance, **ALK & Emma Boulton**, Director, Safety Operations, **Mundipharma & Linda Harmark**, Deputy Director, **Netherlands Pharmacovigilance Centre Lareb**

Medical Devices Panel 6 - Different safety approaches between pharma, devices, and combination products
Moderator: Juan Daccach, Vice President, Global Product Safety, **Merz Aesthetics**
Lisa Benaise, Vice President, Head of Pharmacovigilance, **Calliditas & Judy Barretto**, Global Process Owner, Signal Management Director, **Roche & Antonia Coppin-Renz**, Senior Director, TA Lead Digital Therapeutics & Deputy Global, EU and UK QPPV, **Otsuka**

Digital Transformation Panel 7 - Contrary to popular belief – digital transformation is about people first
Moderator: Sibel Guerler, Head of Innovation, Partnerships and Process Optimisation, Worldwide Patient Safety, **Bristol Myers Squibb**
Marianne Soergel-Ahovi, Drug Safety Lead, **Molecular Partners & Ajibade Adesina**, Director, PV Process Excellence and Learning Strategy, **Bristol Myers Squibb & Emma-Jane Brookes**, Co-Founder, Partner, **Truliant Consulting**

Regulatory Affairs Panel 8 – Labelling and patient safety in non-EU countries
Moderator: Marjan Dzeparoski, RA & PV Manager, **Bionika Pharmaceutical**
Azira Cajic, Head of Division for Pharmacovigilance and Materiovigilance, PV Inspector, **Agency for Medicinal Product and Medical Devices, Bosnia & Sandra Reda**, Quality Assurance Specialist & Deputy QPPV, **OnePharmaMedics & Renato Rjavcec,** Product Director, **ArisGlobal & Donia Al-Bastaky**, Head of Drug Safety, **Kuwait Health Authority & Branka Stojanovic**, Country Safety Lead, Serbia, QPPV, **Pfizer**

Interactive Panel 9 - RESERVED

PV Outsourcing Panel 10 – Evolution of outsourcing
Moderator: Caitlin Keel, Director, Global Head of Case Management & Standards, Global Product Safety and Pharmacovigilance, **United Therapeutics**
Jefferson Guillon, Head of Outsourced Managed Services, **CSL Behring & Kieran O'Donnell**, Independent PV Expert **& Monika Zych**, Director, Pharmacovigilance ECEMEA, **Baxter Corp & Jin Vermaat**, Vice President, Head of PV Affiliate Relations, **Takeda**

AI + AUTOMATION	RISK MANAGEMENT	SIGNAL DETECTION & MANAGEMENT	QUALITY ASSURANCE & COMPLIANCE	CASE PROCESSING	MEDICAL DEVICES	DIGITAL TRANSFORMATION	REGULATORY AFFAIRS	VACCINE SAFETY	PV OUTSOURCING
15.10 **Chair: Hans-Jörg Römming,** Head, Global Patient Safety Operations, **Merck Healthcare KGaA**	15.10 **Chair: Mark Perrott,** Co-Founder, **Axian Consulting**	15.10 **Chair: Marcin Marciniak**, Senior Director, Global Safety and PV Expert WHC, **Gedeon Richter**	15.10 **Chair: Patricia Harding**, Senior Advisor, Medicines Quality Organisation, **Eli Lilly & Co**	15.10 **Chair: Smruti Kothari**, Associate Director, PV Quality Operations, **Alexion, AstraZeneca Rare Disease**	15.10 **Chair: EY**	15.10 **Chair: Ajibade Adesina**, Director, PV Process Excellence and Learning Strategy, **Bristol Myers Squibb**	15.10 **Chair: Attila Olah**, Head, Global Patient Safety, EU & UK QPPV, **Gedeon Richter**	15.10 **Chair:** WIPRO	15.10 **Chair: Gemma Jimenez Sese**, Director, Patient Safety, **Almirall**
15.15 **Fractional stratified k-fold cross validation: A new methodology to investigate training data sufficiency in computer system validation** **Juergen Dietrich**, Senior Lead Data Scientist, Pharmacovigilance, **Bayer**	15.15 **Generic risk minimization doesn't mean low quality but high service** **Michael von Forstner,** Global Head of Clinical Safety and Pharmacovigilance, Biosimilars, **Biogen**	15.15 **Signal evaluation and management: future innovations** **Carolyn Cranfield**, Director, Global Process Owner, PV Excellence, Global Safety, **GSK**	15.15 **Inspections: the good, the bad & the things nobody tells you!** **Mijal Chavda**, Senior Director, Global Head of GxP Inspections & GVP Quality, **Kyowa Kirin**	15.15 **Merging companies ICSR processes in parallel with changing safety databases** **Anna Karin Traff**, Director, ICSR Lead, **AstraZeneca & Anna Liptak Askne**, Director, ICSR Post-Marketing, **AstraZeneca**	15.15 **Speaker presentation** EY	15.15 **Simplifying with automation today: implementing innovation** **Mark Widdowson**, Manager, Innovation, **Bristol Myers Squibb**	15.15 **Challenges in interactions between pharmacovigilance and regulatory departments** **Marco Colombati,** Corporate Pharmacovigilance Compliance Specialist, **ITALFARMACO SPA**	15.15 **Repurposing old vaccines for current and future pandemics** **Nibedita Rath**, Scientific Director, **Open Source Pharma Foundation**	15.15 **Journey to compliance: local PV set up with service providers** **Olaf Schickling**, Senior Director, EEA QPPV, **BeiGene**
15.35 **Gold sponsor presentation** **TRANSPERFECT**	15.35 **The Sobi experience with controlled distribution using electronic systems** **Maria Dahlin**, Director, Global Pharmacovigilance & Patient Safety, **Sobi**	15.35 **Proactive, hypothesis free signal detection** **Elizabeth Smalley**, Director, Product Management Data and Analytics, **ArisGlobal**	15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation EY**	15.35 **Navigating the digital fog: a case for intelligent automation in drug safety** **Sanjeev Srivastav,** Director PV Signal, **RxLogix**	15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation**	15.35 **Effective execution of an early access program** **Fidelma Reid,** Senior Director Vigilance Operations & **Adeline Darchy,** Director Clinical Research, **Voisin Consulting Life Sciences**
15.55 **AI and implications of upskilling: consequences and challenges**	15.55 **Looking to the future; beyond education to behavioural support and proactive risk management**	15.55 **Preparing for the future: signals and surveillance for psychedelic and opioid drugs**	15.55 **Pharmacovigilance intelligence in a global PV system** **Tsambika Fuchs**, Team Lead PV Intelligence and	15.55 **Digital transformation in case processing within Moderna** **Monika Kowalska**, Director, PV Operations ICSR Quality, **Moderna**	15.55 **Speaker presentation EY**	15.55 **Harvesting safety data for scientific decisions** **Sameen Desai**, Executive Director, Head of Worldwide Patient Safety and	15.55 **Global regulatory trends: a futuristic view** **Samah Ragab**, Director, Regulatory Affairs & PV, Middle East, **Organon**	15.55 **Moving from health authority requirements to aggregate reports: ensuring vaccine safety compliance**	15.55 **Outsourcing decisions, strategies and operating models for clinical safety** **Conny Johansson**, Alliance Management Lead, **Roche**

Uwe Gudat, Chief Medical Officer, **Aretaeus sarl**	**Mark Perrott,** Co-Founder, **Axian Consulting**	**Richard Dart**, Executive Director, **Rocky Mountain Poison & Drug Safety**	Performance Management, **Merck Healthcare**			Risk Management IT, **Bristol Myers Squibb**		**Antonella Fretta**, Senior Director, Aggregate Reporting Team Lead, **Pfizer**	
16.15 Networking Break									
AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**QUALITY ASSURANCE & COMPLIANCE**	**CASE PROCESSING**	**MEDICAL DEVICES**	**DIGITAL TRANSFORMATION**	**PATIENT CENTRICITY**	**VACCINE SAFETY**	**PV OUTSOURCING**
16.45 **Chair: IQVIA**	16.45 **Chair:** **Jan Cleerbout**, Deputy EU QPPV, QPPV Office, **Janssen**	16.45 **Chair:** **Linda Bech**, Associate Director, Head of Patient Safety Nordics, **Gilead Sciences**	16.45 **Chair:**	16.45 **Chair:** **Meenakshi Ramachandran**, Manager, Drug Safety, **Molecular Partners**	16.45 **Chair: EY**	16.45 **Chair:** **Ariane Stollenwerk**, Head of Central Europe & Asian Int. Markets, International PhV, **UCB**	16.45 **Chair:** **Olga Panek-Bialkowska,** Associate Director, Global Pharmacovigilance Case Management, **MSD**	16.45 **Chair:**	16.45 **Chair:** **Laura Paolo Boga,** Head of Global Pharmacovigilance, UK & EU QPPV, **Dompe Farmaceutici SPA**
16.50 **Adverse events in the digital age** **Robert Di Giovanni**, Global Patient Safety Lead, **Novartis**	16.50 **Safety risk management strategies: process and oversight** **Melanie Demarke**, Director, Global Process Owner, PV Excellence, Global Safety, **GSK**	16.50 **Quantitative signal detection: a targeted approach** **Tommaso Venturi**, Corporate Pharmacovigilance Risk Assessment Specialist, **ITALFARMACO SPA**	16.50 **From regulatory intelligence to effective implementation of PV regulatory requirements** **Maud Le Petitcorps**, Associate Director, Safety Policy and Process Oversight, **Johnson & Johnson**	16.50 **Importance of quality in case processing** **Kavita Ramji**, Safety Officer, Quality Manager, **Pfizer**	16.50 **Speaker presentation EY**	16.50 **Personal data protection and pharmacovigilance: points to consider** **Sergiy Kryvych**, Senior Drug Safety Officer & Medical Advisor, Deputy Local Pharmacovigilance Responsible Person, **Pfizer**	16.50 **Competency acceleration: enabling leaders in role, putting patients at the centre** **Darren Stewart**, Chief Experience Officer, Competency Accelerator, **Roche**	16.50 **Vaccine pharmacovigilance in outbreak situations** **Heinz Weidenthaler**, Vaccine Pharmacovigilance Expert	16.50 **Successfully outsourcing local safety activities** **Wivina De Waele**, Senior Director, Safety Lead Europe, Global Patient Safety, **Alexion**
17.10 **Transform your drug safety processes with natural language processing** **Jane Reed**, Director, NLP, Safety & Regulatory, **IQVIA**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation** **CHEMOTARGETS**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation** **INDEGENE**	17.10 **Gold sponsor presentation EY**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation** **EXCELYA**
17.30 **Integrating data across regions: analyzing regulatory complexities for AI & automation** **Teresa Saragoca**, Director, Regulatory Affairs & Technical Manager, **ITALFARMACO**	17.30 **Learning lessons on implementation of pregnancy prevention program at a generic set up** **Dnyaneshwar Sanap**, EU & UK QPPV, Head, Regional PV and Global Compliance Training, **Glenmark Pharmaceuticals**	17.30 **Signal detection in drug development: post marketing vs development stages** **Kishore Saha**, Chief Specialist, **Lundbeck**	17.30 **Expectations for QPPV oversight** **Margherita D'Antuono** EU-UK QPPV, **Piramal Critical Care**	17.30 **Speaker presentation**	17.30 **Speaker presentation** **EY**	17.30 **Upskilling the PV profession: attracting and developing PV talent** **Karolina Danysz**, Associate Director, PV Affiliate Relations Liaison, EU-CAN, **Takeda**	17.30 **Speaker presentation**	17.30 **Global safety assessment for the Moderna mRNA COVID-19 vaccine: analysis after 1.3 billion doses** **Veronica Urdaneta**, Senior Director, Global Safety Physician, Pharmacovigilance, **Moderna**	17.30 **Outsourcing effects on QPPVs** **Bert Van Leeuwen**, Deputy QPPV, **Astellas**

17.50 **Close of conference and drinks reception**

Day 2 – Thursday 5th October 2023

08.55 **Chair's remarks**

Morning Plenary

09.00 **The new post-COVID pharmacovigilance landscape**
Patrick Caubel, Chief Safety Officer, **Pfizer**

09.20 **Rethinking safety services - a tech / AI driven future of PV**
Sanjay Vyas, Executive Vice President, Safety & Logistics and Country Head of India, **Parexel**

09.40 **Moving drug safety departments from cost centres to strategic partners**
Fatima Bhayat, Vice President, Head of Global Patient Safety and Chief Safety Officer, **Amgen**

10:00 **Globalizing pharmacovigilance systems to navigate dynamic regulatory landscape with speed and efficiency**

Christina Kim, Senior Director, Vault Safety, **Veeva**

10.20 **Managing pharmacovigilance in Asia-Pacific: challenges and opportunities**
Gloria Bustos, Senior Director, Head of Pharmacovigilance, EMEA & APAC / Global Patient Safety**, Baxter Healthcare**

10.40 **Morning Break & Interactive 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**	**DIGITAL TRANSFORMATION**	**PATIENT CENTRICITY**	**SAFETY IN THE US**	**TRANSLATIONAL SAFETY**
11.30 **Chair:** **Claudia Lehmann**, Vice President, Head, Global Pharmacovigilance Operations & Systems, **Boehringer Ingelheim**	11.30 **Chair:** **Balwant Heer**, Vice President, Global Head of Drug Safety, **Viatris**	11.30 **Chair:** **Howard Snow**, Vice President, Head of Pharmacovigilance, **SOBI**	11.30 **Chair:** **Jeremie Dedessus Le Moutier**, Head of Global PV Excellence, Global Safety, **GSK**	11.30 **Chair:** **Ellen Ravn Englev**, Senior Director, Case Mgmt. & PV system support, Safety Operations, Global Safety, **Novo Nordisk**	11.30 **Chair:** **Begum Benli Peker**, Director, Head of Patient Safety Netherlands & Hub Lead, **Bristol Myers Squibb**	11.30 **Chair:** **Pilar Carrero**, Vice President, Global Safety, **LEO Pharma**	11.30 **Chair:** **Linda Harmark**, Deputy Director, **Netherlands Pharmacovigilance Centre Lareb**	11.30 **Chair:** **David Lilienfeld**, Vice President, Drug Safety and Pharmacovigilance, **Elevar Therapeutics**	11.30 **Chair:**
11.35 **Use of AI in ICSRs: regulatory experiences of AI in PV** **Sarah Vaughan**, Head of Vigilance Development, **MHRA**	11.35 **Impact of pharmacogenomic information on labelling** **Giovanni Furlan**, Worldwide Safety Site Lead & Safety Risk Lead Director, **Pfizer**	11.35 **Challenges of signal detection in orphan medicinal products** **Erika Barbarosie**, Associate Director, Compliance, **Gilead Sciences**	11.35 **Quality management planning for pharmacovigilance** **Marlo Corrao**, Quality Director, Pharmacovigilance Excellence, **GSK**	11.35 **Achieving scalability in case processing capabilities through digitization** **Katarzyna Gruchala**, Director, PV Operations Case Processing, **Moderna**	11.35 **Be prepared! Combination products under MDR (article 117)** **Heinrich Martens**, Vice President, Regulatory Affairs, MedTech, **Fresenius Kabi**	11.35 **Speaker presentation**	11.35 **Updates in patient centricity and pharmacovigilance** **Stephanie Tcherny-Lessenot,** Head of Benefit-Risk Evaluation, **Sanofi**	11.35 **Publishing PV data: What to expect and how to manage** **James Eldridge**, Director, Pharmacovigilance North America, **Y-mAbs**	11.35 **Connecting patient level to molecular data: an ongoing review** **Sibel Guerler**, Head of Innovation, Partnerships and Process Optimisation, WorldWide Patient Safety, **Bristol Myers Squibb**
11.55 **Platinum sponsor presentation**	11.55 **Platinum sponsor presentation**	11.55 **Platinum sponsor presentation**	11.55 **Platinum sponsor presentation**	11.55 **Managing PV for emerging regulators** **Inder Sachdeva**, Global Delivery Leader, **Cognizant & Venkat Venkataramanan**, PV Domain Lead, **Cognizant**	11.55 **Platinum sponsor presentation**	11.55 **WIPRO – Transforming literature management using smart digital automation**	11.55 **Platinum sponsor presentation**	11.55 **Platinum sponsor presentation**	11.55 **Platinum sponsor presentation**
12.15 **Uses of AI beyond case processing: innovative advancements** **Jeremy Jokinen**, Vice President, Global Risk Management & International Patient Safety, **Bristol Myers Squibb**	12.15 **Title TBC** **Shabana Dange**, Senior Director, Global Safety Lead, **Argenx**	12.15 **Underlying diseases and signal detection: challenges with limited patient populations** **Steve Dingman**, Vice President, Head of Pharmacovigilance, **Immunogen**	12.15 **PSMFs on a global or local level** **Hadir Rostom**, President, **ISoP Egypt Chapter** and Lecturer, Faculty of Pharmacy, **Modern Sciences and Arts University**	12.15 **Increasing collaboration and compliance in the area of investigator sponsored studies (ISS)** **Jill Leake**, Director, Head of Clinical Safety Operations, **Merck**	12.15 **Safety considerations for inhaled drug delivery systems** **Santanu Mukhopadhy**, Head, Medical Safety, **VecturaFertin Pharma**	12.15 **The future of PV: impact of digital and social transformation** **Ricarda Tiemeyer**, Head of Pharmacovigilance, DACH Region, **Biogen**	12.15 **Applying consumer centric approaches in risk management** **Dagmara Okla**, Senior Director, Head of Global Safety, Clinical Development & Medical Affairs Quality, Excellence & Governance, EU QPPV, **Haleon**	12.15 **Pregnancy and breastfeeding regulatory landscape assessment: outcomes and proposed solutions** **Nadezda Abramova**, Safety Strategy Lead, **Merck & Leesha Balramsingh-Harry**, Safety Data Acquisition Lead, **Roche**	12.15 **Translational psychiatry: genome guided treatments of psychiatric patients** **George P. Patrinos**, Professor, Department of Pharmacy, **University of Patras &** Adjunct Professor, Department of Genetics and Genomics, **United Arab Emirates University**
12.35 **Artful simplification: transforming pharmacovigilance** **Vivek Ahuja**, Senior Vice President,	12.35 **Benefit-risk 360: enabling real-time safety surveillance oversight and proactive benefit-risk management**	12.35 **Evaluation of drug-induced liver injury risk in pre marketing clinical drug trials**	12.35 **Gold sponsor presentation**	12.35 **Nurturing a culture of drug safety excellence within small and medium pharma** **Humaira Qureshi**, President, **Qinecsa Solutions**	12.35 **Gold sponsor presentation**	12.35 **Gold sponsor presentation**	12.35 **Gold sponsor presentation**	12.35 **Gold sponsor presentation**	12.35 **Gold sponsor presentation**

Global Delivery Excellence, Strategy & Growth, PV, Quality & Regulatory Service Lines, **EVERSANA**	**Kevin Fettermann**, Executive Director, Client Engagement, **Orbit by Feith Systems**	**Sumit Verma**, President, Clinical Safety and PV, **Soterius, Inc**							
12.55 **Automation: the good, the bad and the ugly** **Marina Suvakov**, Global Head Product, Safety Surveillance, **Phillip Morris International**	12.55 **Experience with structured benefit-risk assessment** **Suzanne Foncin**, Senior Director, Head of Safety Analysis and Writing, **UCB**	12.55 **Identifying and managing signals in oncology populations: balancing benefit-risk** **Simon Ashworth**, Head of Pharmacovigilance and Medical Safety, **Ono Pharmaceuticals**	12.55 **Risk assessments for audits** **Gemma Berry Jones**, Associate Director, GVP Quality, **Kyowa Kirin**	12.55 **Transferring to a new safety database: academic clinical trials** **Tuula Ikonen**, Head of Pharmacovigilance Department, **European Organisation for Research and Treatment of Cancer (EORTC)**	12.55 **Physical devices: current challenges and considerations for combination products** **Judy Barretto**, Global Process Owner, Signal Management Director, **Roche**	12.55 **Key opportunities in digital transformation: new tools for innovation** **Melanie Dullemond**, Compliance Head, Medical and PV Quality, **Sanofi**	12.55 **Proportional centralized approach to pharmacovigilance in consumer healthcare** **John Poustie**, EMEA Pharmacovigilance Director, UK QPPV, **Haleon**	12.55 **Risk management approaches: comparisons between the EU and US** **Markus Drumm**, Head of Global Patient Safety Regions, **Merck**	12.55 **Early stage development in cell therapy: ensuring patient safety** **Ilana Frishman**, Safety Director, **Pluri**

13.15 Lunch

14.15 Interactive Panels

AI & Automation Panel 1 –

Risk Management Panel 2 – Benefit risk management and assessments: challenges and opportunities
Moderator: Elian Khazneh, Head of GPS, Benefit Risk Strategy and Management, Global Patient Safety, **Merck**
Sunita Dhar, Executive Medical Group Director, Clinical Safety, **Genentech & Balaji Malla**, Head of Pharmacovigilance, EU & UK QPPV, **Dr Reddy's Laboratories & Alaa Badran**, Quality Assurance Specialist, **RAY CRO & Luiz Lima**, Vice President, Global Patient Safety, Therapeutic Area Lead, Neuroscience, **Ipsen & Anja-Helena Loos**, Director, Biostatistics Oncology, **Merck & Robert Massouh**, Head, Risk Management and Benefit-Risk Evaluation, **GSK**

Signal Detection & Management Panel 3 – Equitable access to pharmacovigilance services
Moderator: Natalie Farrar, Director, Safety and Pharmacovigilance, **ViiV Healthcare**
Olga Menang, Director, Drug Safety and Pharmacovigilance, **Fresenius Kabi SwissBioSim & Leko Mdladla**, Clinical Safety Manager, **ViiV Healthcare & Leith Kwaan**, QPPV, **National Bioproducts Institute & Francoise Sillan**, Vice President, Global Patient Safety, EU & UK QPPV, **Ipsen**

Quality Assurance & Compliance Panel 4 – Modular approaches to PSMFs
Moderator: Monika Manske, Lead Quality Management and Deputy EEA QPPV**, Viatris**
Clara Goncalves, Head, QPPV & Alliance Office, **Grunenthal Group & Emma Wiman**, Director, Regulatory Compliance & Quality, EMENA, **Accord Healthcare & Franziska Rathjens**, Head of Business Process Management & PV Tools, Deputy QPPV, **B Braun & Charlotte Van Haverbeke**, Director, Global Safety, Clinical Development & Medical Affairs (GSM), Process Excellence, **Haleon**

Interactive Panel 5 - RESERVED

Medical Devices Panel 6 – The role of persons responsible for regulatory compliance in postmarketing surveillance for medical devices
Moderator: Milos Stojkovic, Safety Process Director, **Roche**
Fatima Bhayat, Vice President, Head of Global Patient Safety and Chief Safety Officer, **Amgen & Janni Hermansen**, Head, Global Safety Surveillance, Biologics & Devices, **Leo Pharma & James Whitehead**, Senior Director, Devices & Digital Safety, **AstraZeneca**

Digital Transformation Panel 7 – QPPV oversight and digital transformation
Moderator: Ilaria Grisoni, Executive Director, Head of EU & International Pharmacovigilance, QPPV Office and EEA QPPV, **Jazz Pharmaceuticals**
Veronica Fjellstrom, Head, Global Patient Safety & Medical Information, EU & UK QPPV, **Karo Pharma AB & Klaus Bitsch-Jensen,** Director, Head of QPPV Office, EU QPPV, **ALK & Maria-Jose Reneses**, Director, Deputy EU QPPV and Head of PSMF, **Takeda & Raphael Van Eemeren**, Senior Director, EU/UK QPPV, Global Patient Safety, **Amgen**

Patient Centricity Panel 8 – Real world evidence in patient support programmes
Moderator: Garry Flounders, Senior Process Lead, Biosimilars, **Biogen**
Alina Tudor, Senior Director, Pharmacovigilance, **Kyowa Kirin International & Mary Lynne Van Poelgeest-Pomfret**, President, **World Federation for Incontinence and Pelvic Pain (WFIPP) & Manal Younus**, Advisory Board Member, Patient Engagement Co Lead, **ISoP & Tanja Fahlbusch**, Deputy Head, International Pharmacovigilance Business Process Management, **Roche**

Quality Assurance & Compliance Panel 9 – Challenges and best practices for PV legislation implementation
Moderator: Emmanuelle Pines, Head of Safety Policy & Process Oversight, QPPV Office, **Janssen**
Diane Halle, Senior Manager, Pharmacovigilance Quality Assurance, **Alnylam Pharmaceuticals & Anne Raison**, Head of Quality and Medical Compliance Management, **Roche & Ranjana Khanna**, Director, Head of PV, Quality Assurance, **Nestle Health Sciences & Sophie Radicke**, Head of GPvP and Senior Pharmacovigilance Inspector, **MHRA**

Translational Safety Panel 10 – Pharmacovigilance in cell and gene therapies
Moderator: David Chonzi, Global Head of PVE, **Instil Bio**
Ram Vempati, Former Head of Pharmacovigilance, **Arcellx**

AI + AUTOMATION	RISK MANAGEMENT	SIGNAL DETECTION & MANAGEMENT	QUALITY ASSURANCE & COMPLIANCE	CASE PROCESSING	MEDICAL DEVICES	DIGITAL TRANSFORMATION	PATIENT CENTRICITY	SAFETY IN THE US	TRANSLATIONAL SAFETY

15.10 **Chair:** **Reserved for Aris-Global**	15.10 **Chair:** **Eva van Engelen,** Director, Patient Safety**, Gilead Sciences**	15.10 **Chair:** **Ellen Bonagua**, Executive Director, Drug Safety and Pharmacovigilance, **Insmed Incorporated**	15.10 **Chair:** **Wasim Anwar**, Vice President & Deputy QPPV, Global Safety, **Novo Nordisk**	15.10 **Chair:** **Daniela Di Cosmo**, Senior Safety Advisor, Global Safety, **Ferring**	15.10 **Chair:** **Milos Stojkovic**, Safety Process Director, **Roche**	15.10 **Chair:** **Peter De Veene**, QPPV, **Incyte**	15.10 **Chair:** **Devi Padmanaban**, Executive Director, Drug Safety, **Neurocrine Biosciences**	15.10 **Chair:** **Ram Vempati**, Former Head of Pharmacovigilance, **Arcellx**	15.10 **Chair:**
15.15 **How artificial intelligence and automation can change drug safety management** **Marco Tuccori**, Pharmacovigilance Manager, **University Hospital of Pisa &** Coordinator, **Tuscan Regional Centre of Pharmacovigilance &** Co-Chair, **ISoP Scientific Board**	15.15 **PV and pharmaceutical manufacturing** **Rainer Heissing**, Executive Director, Deputy EU/UK QPPV, **Gilead Sciences**	15.15 **Reimagining signal detection in LMICs** **Leko Mdladla**, Clinical Safety Manager, **ViiV Healthcare**	15.15 **PSMF possible improvements for collecting information from subject matter experts and periodic update** **Isabella Caramuta**, Deputy QPPV, Pharmacovigilance Manager, **Shionogi Europe**	15.15 **Evolution of quantitative and qualitative case management data** **Caitlin Keel**, Director, Global Head of Case Management & Standards, Global Product Safety and Pharmacovigilance, **United Therapeutics**	15.15 **Misuse or off-label use of medical devices** **Daniela Gramaglia**, Medical Device Vigilance Manager, **Chiesi**	15.15 **Use of a database for the management of pharmacovigilance agreements** **Marko Strott**, Associate Director, Partnership Management, Global Patient Safety, **Merck**	15.15 **Safety real world evidence for treatment decisions** **Jost Leemhuis**, Safety Science Partner and Global Business Lead, **Roche**	15.15 **Overview of REMS program development** **Lilliam Fernandes**, Director, Clinical Safety and Pharmacovigilance, **Adaptimmune**	15.15 **Translating preclinical safety findings into the design of the first in human study** **Henk Johan Streefkerk**, CEO & Medical Director, **Amarna Therapeutics**
15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation**	15.35 **Gold sponsor presentation**
15.55 **Applications of machine learning in safety surveillance & risk management** **Philip Jones**, Senior Director, Disease Area Cluster Lead, Inflammation & Immunology, **Pfizer**	15.55 **Implementation of digital tools for risk management** **Klaudija Marijanovic Barac**, Senior Director, Global Patient Safety & PV – TPC, Deputy EU & UK QPPV, **Teva Pharmaceuticals**	15.55 **Future directions in signal detection, evaluation and communication** **Vipin Sethi**, Head of Global Pharmacovigilance and Medical Affairs, **Cadila Pharma**	15.55 **PV quality management in biotechs** **Gemma Sayers**, Director, Pharmacovigilance Quality Management Lead, **Regeneron Pharma**	15.55 **Accommodating local and regional reporting requirements in a global PV organization** **Bartosz Olas**, Principal Safety Data Manager, Global Pharmacovigilance Case Management, **MSD**	15.55 **Mapping surveillance across departments: combination products** **Janni Hermansen**, Head, Global Safety Surveillance, Biologics & Devices, **Leo Pharma**	15.55 **Bringing in outsourced activities** **Irina Maria Ciubotaru**, Head of Global Pharmacovigilance and Drug Safety, **ITM Isotopen Technologien Munchen**	15.55 **PV hubs powering affiliate transformation towards greater patient centricity** **Michael Becker**, International PV, Global Head, PV Hubs, **Roche**	15.55 **Safety reporting requirements and assessments for investigational new drugs (IND) in the US** **Jaylaxmi Nalawade**, Associate Director, Pharmacovigilance and REMS, **Lupin Inc**	15.55 **Applying health literacy principles: advances and innovations** **Kate Anteyi**, Director, Global Safety Physician, **Moderna**
16.15 Networking Break									
AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**QUALITY ASSURANCE & COMPLIANCE**	**CASE PROCESSING**	**MEDICAL DEVICES**	**DIGITAL TRANSFORMATION**	**PATIENT CENTRICITY**	**SAFETY IN THE US**	**TRANSLATIONAL SAFETY**
16.45 **Chair:** **Aman Wasan,** Chief Commercial Officer, **ArisGlobal**	16.45 **Chair:** **Iva Zgombic Rukavina**, Medical Affairs and Pharmacovigilance Senior Associate, **Belupo**	16.45 **Chair:** **Karin Thelen**, Head of Drug Safety, **Cardior Pharmaceuticals**	16.45 **Chair:** **Jolanda De Bruijne**, Executive Director, PV Compliance, Oversight & Process Excellence (COPE), Pharmacovigilance Operations, **Astellas**	16.45 **Chair:**	16.45 **Chair:**	16.45 **Chair:**	16.45 **Chair:** **Gabrielle Amselem**, Director, Patient Safety Excellence, **Alexion, AstraZeneca Rare Disease**	16.45 **Chair:**	16.45 **Chair:**
16.50 **Intelligent automation in PV** **Ranga Reddy**, Director, Global Head of Drug Safety Technologies, **CSL Vifor**	16.50 **Failures of risk minimization measures: common findings when things go wrong** **Natasa Mihajlovic**, Managing Director, **NostraPharma Ltd**	16.50 **Peculiarities of signal detection in paediatric population** **Sutirtha Mukhopadhyay**, Senior Patient Safety Physician, **Boehringer Ingelheim**	16.50 **The art of maintaining a compliant PV system** **Santiago Schiaffino**, Medical Director, Senior Patient Safety Physician, **Astra Zeneca**	16.50 **Speaker presentation**	16.50 **Substance based medical devices** **Joan D'Souza**, Independent PV Expert	16.50 **Speaker presentation**	16.50 **QPPV gatekeeper operating model: driving efficient QPPV oversight** **Jessica Marlind Wurtele**, Director, Patient Safety Excellence, **AstraZeneca**	16.50 **Speaker presentation**	16.50 **Potential drug safety risks associated with drug development** **Galyna Cordero**, QPPV, Head of Pharmacovigilance Department, **JSC Farmak**
17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation**	17.10 **Gold sponsor presentation**
17.30 **Speaker presentation**	17.30 **Risk management planning in clinical development** **Mircea Ciuca**, Independent PV Expert	17.30 **Speaker presentation**	17.30 **First experience with IRIS platform for EMA GVP inspection**	17.30 **Speaker presentation**	17.30 **Speaker presentation**	17.30 **Speaker presentation**	17.30 **Speaker presentation**	17.30 **Speaker presentation**	17.30 **Speaker presentation**

			Julia Appelskog, EU QPPV, Global Vaccine Safety, **Novavax**						

17.50 Close of conference