WORLD DRUGSAFETY CONGRESS EUROPE

World Drug Safety Europe Congress 2022

27-29th September 2022 – Amsterdam – Amsterdam RAI

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

1. **Mariette Boerstoel Streefland,** SVP Patient Safety, Chief Safety Officer**, AstraZeneca**
2. **Jens-Ulrich Stegmann**, Senior Vice President, Head Clinical Safety and Pharmacovigilance, EU QPPV**, GSK**
3. **Jijo James,** Chief Medical Officer, Medical Devices, **Johnson & Johnson**
4. **Fatima Bhayat**, Vice President, Head of Global Patient Safety and Chief Safety Officer, **Amgen**
5. **Shinobu Uzu**, Senior Executive Director, **Pharmaceuticals and Medical Devices Agency, Japan**
6. **Stewart Geary**, Global Safety Officer & Senior Vice President, **Eisai**
7. **Asif Mahmood**, Chief Safety Officer, Global Clinical Safety & Pharmacovigilance, **Medicago**
8. **Marcin Kruk**, Senior Director, Drug Safety Unit Regional Head, Europe, Africa & Middle East, **Pfizer**
9. **Gloria Bustos,** Senior Director, Head of Pharmacovigilance, EMEA & APAC / Global Patient Safety**, Baxter Healthcare**
10. **Jane Carroll**, Vice President, Medical Excellence and PV Operations, **Moderna**
11. **Jeremy Jokinen,** Vice President, Global Risk Management & International Patient Safety, **Bristol Myers Squibb**
12. **Juhaeri Juhaeri**, VP & Head, Epidemiology and Benefit-Risk, **Sanofi**
13. **Magnus Ysander**, EU & UK QPPV & Head, Pharmacovigilance Excellence, **Astra Zeneca** & **Alexion**
14. **Adrian Maynier**, Head of Safety Systems, **UCB**
15. **Raj Long,** Deputy Director, Integrated Development, Global Health, **Bill and Melinda Gates Foundation**
16. **Wasim Anwar**, Vice President & Deputy QPPV, Global Safety, **Novo Nordisk**
17. **Andrew Bate**, VP & Head, Safety Innovation & Analytics, Global Safety, **GSK**

18. **Pilar Carrero**, Vice President, Global Safety, **LEO Pharma**
19. **Heike Von Treichel**, Head of PV QMS and Deputy QPPV, **Merck Healthcare**
20. **Attila Olah**, Head Global Patient Safety, EU/UK-QPPV**, Gedeon Richter**
21. **Lisa Benaise,** VP, Head of Pharmacovigilance, **Calliditas**
22. **Marie Pierre Caby**, EEA/UK QPPV, **Moderna**
23. **Yusuf Tanrikulu**, Deputy EU QPPV, **Roche**
24. **Delphine Bertram**, Head, Safety Vigilance, EMEA Operations, EU QPPV, **Santen**
25. **Adrian Roth**, Principal Scientific Director, Personalised Health Care Safety, **Roche**
26. **Joel Johansen**, Vice President, Global Head of PV Compliance and PV Head EMEA, **Kyowa Kirin International**
27. **Sabine Jeck-Thole**, Senior Advisor, **Boehringer Ingelheim**
28. **Lisa Lawrence-Miyasaki**, Vice President, Drug Safety & Pharmacovigilance, **Coherus BioSciences**
29. **Jean-Christophe Delumeau,** Board Director, **Institute of Pharmacovigilance**
30. **David Martin**, Vice-President, Clinical Safety and Risk Management, **Moderna**
31. **Emmanuelle Pines**, Head of Safety Policy & Process Oversight, QPPV Office, **Janssen**
32. **Clémence Elie**, VP, Head of Global Patient Safety, dQPPV, **Ipsen**
33. **Lucy Hampshire**, Associate Vice President, Head, Medicines Quality Organisation International, **Eli Lilly & Co**
34. **Jan Cleerbout,** Deputy EU QPPV, QPPV Office, **Johnson & Johnson**
35. **James Milligan,** Independent PV Expert
36. **Howard Snow**, Head of Pharmacovigilance, **Hengrui Europe Therapeutics Medicine**
37. **Mircea Ciuca**, Global Therapeutic Area Head, Global Clinical Safety & PV, **CSL Behring**

38. **Sylvie Bartus**, Senior Director, Clinical Safety Global, Clinical Affairs, Surgical Structural Heart, **Edwards Lifesciences**
39. **Jeremie Dedessus Le Moutier**, Head of Global PV Excellence, Global Safety, **GSK**
40. **James Whitehead**, Patient Safety Medical Device Lead, **AstraZeneca**
41. **Michael von Forstner,** Head of Clinical Safety and Pharmacovigilance, Biosimilars, **Biogen**
42. **Phil Tregunno,** Group Manager, Vigilance, Intelligence and Research**, Medicines & Healthcare Products Regulatory Agency**
43. **Ricarda Tiemeyer**, Head of Pharmacovigilance, DACH Region, **Biogen**
44. **Willemijn van der Spuij**, Executive Director, Worldwide Patient Safety International, **Bristol Myers Squibb**
45. **Fabio De Gregorio**, Vice President, Head of Drug Safety Europe, **Shionogi Europe**
46. **Marie Pihl**, Senior Director, PV Processes, Partnerships & Contracts, **AstraZeneca**
47. **Anna Karin Traff**, Director, PS Operations, Technology & Analytics, **AstraZeneca**
48. **Raphael Van Eemeren**, Director, EU/UK QPPV, **Amgen**
49. **Gabrielle Amselem**, Director, PV Excellence Expert, **Alexion, AstraZeneca Rare Disease**
50. **Linda Helmsfors**, QPPV & Head of Pharmacovigilance, **Bluefish Pharmaceuticals Group**
51. **Clara Goncalves**, Head QPPV & Alliance Office, **Grunenthal Group**
52. **Mahalakshmi Elluri**, EU QPPV, **Amryt Pharma**
53. **Rachel McDermott**, Drug Safety Physician, **Shionogi Europe**
54. **Magda Daudin,** Director, Pharmacovigilance QA Lead, **Idorsia**
55. **Anna Luk**, Senior Director, Systems, Global Patient Safety, **Gilead Sciences**
56. **Vivek Ahuja**, Vice President – Medical Affairs & Head, Global Pharmacovigilance, **Sun Pharmaceuticals**
57. **Frédérique Delannois**, Director, Safety evaluation & Risk Management Team Leader, Global Safety, **GSK**

58. **Sina Schader,** EEA and UK QPPV, **AbbVie**
59. **TBC Achint Kumar**, EU QPPV, **Biogen**
60. **Ayesha Bailey**, IT Business Partner, **Roche**
61. **Milos Stojkovic**, Senior Safety Scientist, **Smith+Nephew**
62. **Dennis Vargo**, VP, Head of Drug Safety and Pharmacovigilance, **Akebia Therapeutics**
63. **Zuzana Kusynova**, Lead, Policy, Practice & Compliance, **International Pharmaceutical Federation**
64. **Camilla Hammerum**, Vice President, Global Patient Safety, Neuroscience Therapeutic Area Head, **Ipsen**
65. **Michael Dooley**, PV Manager and Deputy QPPV, **Amryt Pharma**
66. **Mette Stie Kallesoee**, Deputy QPPV, **Leo Pharma**
67. **Nikolas Minder,** Scientific Business Director, **Roche**
68. **Andrew Erdman,** Vice President, Global Head of Early Development Safety, Late Stage and Marketed Medicines Safety, **Genentech**
69. **Alina Tudor,** Senior Director, Pharmacovigilance, **Kyowa Kirin International**
70. **Claudia Lehmann**, VP, Head, Global Pharmacovigilance Operations & Systems, **Boehringer Ingelheim**
71. **Max Waschbusch**, TA Head Cardiovascular and Metabolism, **CSL Behring**
72. **Bert Van Leeuwen**, Deputy QPPV, **Astellas**
73. **Marcin Marciniak**, Senior Director, Global Safety and PV Expert WHC, **Gedeon Richter**
74. **Katarzyna Gruchala**, Director, PV Operations Case Processing, **Moderna**
75. **Monika Kowalska**, Director, PV Operations ICSR Quality, **Moderna**
76. **Tanja Peters**, Head, Global Patient Safety, Neurology & Immunology, Fertility, **Merck Healthcare KGaA**
77. **Hans-Jörg Römming,** Executive Director, Head of GPS Operations, **Merck Healthcare KGaA**

78. **Rudi Scheerlinck**, Safety Strategy Lead, **Merck Healthcare Oncology**
79. **Andrea Maulwurf**, Head of Corporate Pharmacovigilance, Global Heading QPPV, **Allergy Therapeutics**
80. **Alex Bica**, Senior Director, Global Clinical Safety and Pharmacovigilance, Global R&D**, CSL Behring**
81. **Veronica Urdaneta**, Senior Director, Global Safety Physician, Pharmacovigilance, **Moderna**
82. **Christopher Flood**, Senior Director, Safety Operations, **Erasca Inc**
83. **Riti Shah**, Medical Director, Pharmacovigilance, **Chiesi**
84. **Panagiota Reiter**, Senior Director, Safety Physician, **Genmab**
85. **Jessica Chinault-Jalboot**, Head of Quality & Compliance, GCP/GVP & Regulatory, **AlloVir**
86. **Dany Ward**, Senior Director, Clinical Safety & Risk Management, **AlloVir**
87. **James Eldridge**, Director, Pharmacovigilance North America, **Y-mAbs**
88. **Abiola David**, Director, Medical Information, Safety Services & Vendor Management, **GSK**
89. **Ketan Marulkar**, Senior Pharmacovigilance Officer, Deputy QPPV, **Chanelle Pharma**
90. **Julia Appelskog**, Head of QPPV Office, **Novavax**
91. **Mafora Florah Matlala**, Vigilance Manager, **South African Health Products Regulatory Authority (SAHPRA)**
92. **Feryal Tanriverdio,** Head of Patient safety and Pharmacovigilance Digital Innovation, **Boehringer Ingelheim**
93. **Jolanda De Bruijne**, Executive Director PV Compliance, Oversight & Process Excellence (COPE), Pharmacovigilance Operations, **Astellas**
94. **Minhaj Obediullah**, Head, Compliance and Risk Management, **Novartis**
95. **Mina G Awad,** Pharmacovigilance Manager and QPPV, Middle East, **Kyowa Kirin International**
96. **Amina Baljic**, Head of PV Ops & PV Excellence, **Grunenthal Group**
97. **Adriana Radu**, Head, Drug Safety Evaluation & QPPV, **Mundipharma**

98. **Luke Keitel**, Head of GCP/GVP Audit and Quality Risk Management, **Lundbeck**
99. **Teodora Perger**, Director, Deputy Head of Safety & PV, **ViiV Healthcare**
100. **Jane Feron**, Senior Director, Patient Safety Risk Management, **AstraZeneca**
101. **Peter De Veene**, QPPV, **Incyte Biosciences**
102. **Peter Kohut,** Pharmacovigilance Lead, **Alvotech**
103. **Ranga Reddy**, Global Head of Drug Safety Technologies, **Vifor Pharma**
104. **Israel Gutierrez**, VP, Drug Safety and Pharmacovigilance, **Compugen**
105. **Sibel Guerler**, Head of Innovation, Partnerships and Process Optimisation, WorldWide Patient Safety, **Bristol Myers Squibb**
106. **Nicole Avalos,** Director, Global Clinical Safety & Pharmacovigilance, Head of Safety Sciences, Reporting & Analytics, **CSL Behring**
107. **Cristina Vara Navarrete**, European Pharmacovigilance Manager & Local Safety Officer for Germany and Austria, **Seagen**
108. **Signe Nielsen**, Manager of Safety Operations, **ALK**
109. **Antonella Fretta**, Senior Director, Aggregate Reporting Team Lead, **Pfizer**
110. **Wivina De Waele**, Director, EMEA, Global Drug Safety, **Alexion**
111. **Katrien Soleme**, Senior Director, Pharmacovigilance and Life Cycle Management Quality, **Bristol Myers Squibb**
112. **Claudia Bäcker**, Head of Audit, Inspection, Deviation and CAPA Management, **Merck Healthcare**
113. **Dmytro Horilyk**, CEO, **DrugCards**
114. **Olena Matveeva**, Manager, Pharmacovigilance Quality & technical Officer for Pharmacovigilance, **Acino Pharma & WHO**
115. **Sandra Reda**, Quality Assurance Specialist & Deputy QPPV, **OnePharmaMedics**
116. **Dnyaneshwar Sanap,** EU & UK QPPV, Head, Regional PV and Global Compliance Training, **Glenmark Pharmaceuticals**
117. **Michael Murphy,** Executive Director, Head of Pharmacovigilance Operations, **Amgen**

118. **Maritess Esguerra**, Senior PV Process Director, **Genentech**
119. **Sean Burke**, Senior Director, Regional Lead, International Pharmacovigilance, **MSD**
120. **Ranjana Khanna,** Director, Head of PV Quality Assurance**, Nestle Health Sciences**
121. **Isabel Kloer**, Lead, Risk Management Physician and Product Owner, **Boehringer Ingelheim**
122. **Mattia Calissano,** Head of Drug Safety and Risk Management, Italy & UK QPPV**, Orchard Therapeutics**
123. **Klaus Bitsch-Jensen**, Deputy QPPV, **ALK**
124. **Tjark Reblin,** Global Head Drug Safety and Risk Management**, Vifor Pharma**
125. **John Solomon,** Head of Pharmacovigilance, UK and Ireland, **Sanofi**
126. **Ashlyn Bassiri**, VP of Immunology, **Kriya Therapeutics**
127. **Tanuja Halady,** Head of GPS Oncology Group III, Medical Safety Global Patient Safety, **Merck**
128. **Rita Lobatto,** Senior Director, Pharmacovigilance, Deputy QPPV, **Pharming Group**
129. **Yvonne Nanciu**, Head of Pharmacovigilance Germany, **Bayer**
130. **Patricia Harding**, Senior Advisor, Medicines Quality Organisation, **Eli Lilly & Co**
131. **Samah Ragab**, Director, Regulatory Affairs & PV, Middle East, **Organon**
132. **Sarah Al-Musaed**, Regulatory Affairs and Drug Safety Specialist, **Grunenthal Group**
133. **Jutta Syha**, Independent PV Expert
134. **Ariane Stollenwerk**, Safety Leader, Germany, Austria and Switzerland, **UCB**
135. **Theresa Markey**, Director and Head, Safety Operations, **Corcept Therapeutics**
136. **Fabian Heisig,** SVP Head Global Drug Safety & Qualified Person for Pharmacovigilance, **Grunenthal Group**
137. **Annemette Boye**, Deputy QPPV, **Seagen**

138. **Roberta Amodeo**, Associate Director, ECP Regional Management, International Pharmacovigilance, **Biogen**
139. **Lambert Creuwels**, Senior Medical Safety Adviser, **Lundbeck**
140. **Amalia Alexe**, PV Office and Liaison Lead, QPPV, PRRC Office, **Novartis**
141. **Margarita Zhelyazkova**, Global Pharmacovigilance and Compliance Specialist, **Independent**
142. **Jessica Hansen**, Patient Engagement Manager, **Bayer**
143. **Mijal Chavda**, Director, Global GxP Inspections & GVP Quality, **Kyowa Kirin**
144. **Klaudija Marijanovic Barac,** Senior Director, Global Patients Safety & PV – TPC, **Teva Pharmaceuticals**
145. **John Reinhard Pietzsch**, Head of Data Science & Insights**, Bayer**
146. **Mark Widdowson**, Manager, Digital Insights and Innovation, **Bristol Myers Squibb**
147. **Julie Girod**, Associate VP, Global Head of Case Management and Medical Evaluation, **Sanofi**
148. **Chinmaya Mahapatra,** Founder & President, **Global Pharmacovigilance Society** & Pharmacovigilance Associate, **Indian Pharmacopeia Commission**
149. **Stephanie Tcherny-Lessenot**, Head of Benefit-Risk Evaluation, **Sanofi**
150. **Sabine Fuerst-Recktenwald**, Principal Medical Director Personalized Health Care (PHC) Safety, **Roche**
151. **Pav Rishiraj**, Director, Head of Patient Safety, **Ipsen** & PV Expert Chair, **ABPI**
152. **Dimitris Zampatis**, Independent PV Expert
153. **Claudia Ana Ianos**, Senior Director, Safety Risk Lead, Pfizer
154. **Eva van Engelen,** Director, Global Patient Safety**, Gilead Sciences**
155. **Tea Babic**, Director, Audits and Inspections, **Teva Pharmaceuticals**
156. **Deanna Montes de Oca,** Global Head of PV Case Management**, Moderna**

157. **Amgad Shebl,** Senior Director, Global Safety Lead, Immunology**, CSL Behring**
158. **Gemma Jimenez Sese,** Corporate Drug Safety Head, EU QPPV, **Almirall**
159. **Katerina Sakkoula**, Head of Affiliate Global Interface, **Roche**
160. **Jacquelien Noordhoek**, President**, CF Europe**
161. **Monika Manske,** Lead Quality Management and Deputy EEA QPPV**, Viatris**
162. **Giovanni Furlan,** Safety Risk Lead Director, **Pfizer**
163. **TBC Agata Higgerson**, Senior Safety Scientist, **Roche**
164. **Omar Aimer**, Lead, Medical Device Safety, Special Interest Group, **ISoP**
165. **TBC Hildia Schreuder**, Country Safety Head, Netherlands, **Sanofi**
166. **Maria Maddalena Lino**, Safety Risk Lead Director, COVID Vaccine, **Pfizer**
167. **Laura Paolo Boga,** Head of Global Pharmacovigilance, UK & EU QPPV, **Dompe Farmaceutici SPA**
168. **Daniela Di Cosmo,** Senior Pharmacovigilance Manager, Global Pharmacovigilance**, Ferring**
169. **Jennifer Kane**, Senior Director, Pharmacovigilance Operations & Compliance, **Arcus Biosciences**
170. **Nicola Wallis**, Executive Director, PV Innovation, UK QPPV, **Beigene**
171. **Ajibade Adesina**, Associate Director, PV Process Excellence and Learning Strategy, **Bristol Myers Squibb**
172. **Fee Alexandra Gedlich**, Head of Local Patient Safety and Pharmacovigilance, Germany, **Boehringer Ingelheim**
173. **Lynne Comiskey**, QPPV Compliance and Program Manager, **Sanofi**
174. **Daniela Gramaglia**, Medical Device Vigilance Manager, **Chiesi Farmaceutici**
175. **Marija Briede,** Head of Pharmacovigilance, QPPV, **Grindeks**
176. **Lionel Van Holle,** Founder**, OpenSourcePV**

177. **Wei Wannhoff**, Safety Data Analyst, Global Patient Safety, **Merck Healthcare KGaA**

178. **Vivienne van de Walle**, Medical Director, **Precare Trial and Recruitment Research Centre**

179. **Vivien Stettner**, Regional PV Director, WEC, International PV Op Excellence, **AbbVie**

180. **Annie Moisan**, Program Director, HOPE, **Wellcome Leap**

181. **TBC Mariona Gelabert**, Pharmacovigilance Regional Manager, **Viatris**

182. **Alejandra Padovani**, Safety Director, **Roche**

183. **Marjan Dzeparoski**, RA and PV Manager, **Bionika Pharmaceuticals**

184. **Mike de Leeuw**, CEO, **My Life Technologies**

185. **Tatjana Ajhler Duretek**, Head of Medical Affairs and Pharmacovigilance, EU QPPV, **Belupo Pharmaceuticals & Cosmetics**

186. **Belen Granell Villen,** Quality and Safety Policy Executive**, The Association of the British Pharmaceutical Industry**

187. **Vipin Sethi,** Head of Global Pharmacovigilance and Medical Affairs**, Cadila Pharmaceutical Limited**

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

189. **Galina Cordero,** Head of Pharmacovigilance Department, QPPV, **JSC Farmak Ukraine**

190. **Mary Lynne Van Poelgeest-Pomfret,** President**, World Federation for Incontinence and Pelvic Pain (WFIPP)**

191. **Talia Milosevic,** Senior Manager, Clinical Safety, Surgical Structural Heat**, Edwards Lifesciences**

192. **Christine Von Raesfeld**, Founder, **People with Empathy**

193. **Sutirtha Mukhopadhyay,** Senior Patient Safety Physician, **Boehringer Ingelheim**

194. **Hadir Rostom**, President, **ISoP Egypt Chapter** and Lecturer, Faculty of Pharmacy, **Modern Sciences and Arts University**

195. **Nathalie Joffre,** Global Vigilance Manager EU-QPPV / RPV Vigilance, **Biocodex**

196. **Siva Kumar Buddha,** Global Pharmacovigilance Physician, Senior Manager, **Teva Pharmaceuticals**

197. **Shahinaz Badr**, Pharmacovigilance Consultant and PVQA Auditor, **Pharma Quality Europe**

198. **Manni Kuthiala,** PV Country Cluster Lead - LATAM, **Roche**

199. **Marco Colombati,** Corporate Pharmacovigilance Compliance Specialist**, ITALFARMACO SP**

200. **Tommaso Venturi**, Corporate Pharmacovigilance Risk Assessment Specialist, **ITALFARMACO SPA**

Day 1 – Tuesday 27th September 2022

08.55 **Chair's remarks**
Mariette Boerstoel Streefland, SVP Patient Safety, Chief Safety Officer**, AstraZeneca**

Morning Plenary

09.00 **Pharmacovigilance innovations serving the fight against the COVID-19 pandemic**
Marcin Kruk, Senior Director, Drug Safety Unit Regional Head, Europe, Africa & Middle East, **Pfizer**

09.20 **Smart Safety Surveillance (3S) - "AFRIVIGILANCE" challenges and innovative approaches in COVID vaccine safety in Africa**
Raj Long, Deputy Director, Integrated Development, Global Health, **Bill and Melinda Gates Foundation**

09.40 **Integrating real-world data in your pharmacovigilance workflow**
Bruce Palsulich, Vice President of Product Strategy, **Oracle**

10:00 **Moments that Matter: Value realised through bold ideas, fearless moves and trusted relationships**
Amanda Bowles, Managing Director, **Kevin Sullivan,** Principal, **Deloitte & Jane Carroll,** Vice President, Medical Excellence and PV Operations, **Moderna**

10.20 **Panel Discussion: Utility and applicability of automation and AI: across large to small organisations (5x panellists including platinum)**
Chair: Mariette Boerstoel Streefland, SVP Patient Safety, Chief Safety Officer**, AstraZeneca**
Jens-Ulrich Stegmann, Senior Vice President, Head Clinical Safety and Pharmacovigilance, EU QPPV**, GSK**
Jane Carroll, Vice President, Medical Excellence and PV Operations, **Moderna**
Hans-Jörg Römming, Head, Global Patient Safety Operations, **Merck Healthcare KGaA**
Israel Gutierrez, VP, Drug Safety and Pharmacovigilance, **Compugen**

booth 33 ARIS 10:40

11.00 **Morning Break**

Track 1	**Track 2**	**Track 3**	**Track 4**	**Track 5**	**Track 6**
AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**QUALITY ASSURANCE & COMPLIANCE**	**CASE PROCESSING**	**MEDICAL DEVICES**
11.40 **Chair:** **Jane Carroll**, VP, Pharmacovigilance and Medical Operations, **Moderna**	11.40 **Chair:** **Amgad Shebl**, Senior Director, Global Safety Lead, Immunology, **CSL Behring**	11.40 **Chair: Howard Snow**, Head of Pharmacovigilance, **Hengrui Europe Therapeutics**	11.40 **Chair: Valentina Mancini,** Senior Director Pharmacovigilance, QPPV**, Shionogi Europe & TransCelerate**	11.40 **Chair: Deanna Montes de Oca,** Global Head of PV Case Management, **Moderna**	11.40 **Chair:** **Alex Charitou,** Partner, **EY**
11.45 **Enabling patient safety through AI and Automation** **Jeremy Jokinen**, Vice President, Global Risk Management & International Patient Safety, **Bristol Myers Squibb**	11.45 **The role of pharmacogenomics in drug safety** **Giovanni Furlan**, Safety Risk Lead Director, **Pfizer**	11.45 **New developments in signal management in pharmacovigilance** **Dimitris Zampatis**, Independent PV Expert	11.45 **Metrics to manage quality assurance in pharmacovigilance: concerns for regulators** **Ranjana Khanna,** Director, Head of PV, Quality Assurance, **Nestle Health Sciences**	11.45 **Considerations for patient support and market research program cases** **Daniela Di Cosmo**, Senior Pharmacovigilance Manager, Global Pharmacovigilance, **Ferring**	11.45 **Legal "Hot Topics" in the use of AI in Drug Safety: Classification, Liability and Better Regulation** **Heinz-Uwe Dettling,** Head of Life Science Law and Digital Law and AI Working Group, **EY**
12.05 **Solving the PV technology puzzle in the digital era**	12.05 **Thinking with the End in Mind: Balancing Global & Local Needs to Successfully Manage the**	12.05 **Ebeling & Assoc.**	12.05 **Oversight of quality and compliance by the QPPV**	12.05 **How did we turn a 5-step ICSR process into 147 (or more) steps?**	12.05 **Safety by design in digital health: Adopting a proactive approach to clinical risk and safety allows**

Jen Markey, Chief Sales and Marketing Officer & **Martin Holm-Petersen,** CEO, **Insife**	**Risk Minimization Roll Out** **Kevin Fetterman,** Executive Director of Client Engagement, **Orbit by Feith Systems**		**Minyar Chelly,** Activity Manager QPPV, **ProductLife Group**	**Ian Nicholls,** CEO, **explic8**	**greater innovation and speed to market.** **Alex Charitou,** Partner Life Sciences, **EY**
12.25 **Enhanced data collection and signal detection through MHRA's use of technology** **Phil Tregunno,** Group Manager, Vigilance, Intelligence and Research**, Medicines & Healthcare Products Regulatory Agency**	12.25 **Overarching approach to Benefit Risk Assessment for Drugs and Biologics** **Siva Kumar Buddha,** Global Pharmacovigilance Physician, Senior Manager, **Teva Pharmaceuticals**	12.25 **From detection to confirmation of signals** **Nathalie Joffre**, Global Vigilance Manager EU-QPPV / RPV Vigilance, **Biocodex**	12.25 **PSMF going global** **Sabine Jeck-Thole**, Senior Advisor, **Boehringer Ingelheim**	12.25 **Safety data migration: integrating PV systems** **Marco Colombati,** Corporate Pharmacovigilance Compliance Specialist, **ITALFARMACO SPA & Tommaso Venturi**, Corporate Pharmacovigilance Risk Assessment Specialist, **ITALFARMACO SPA**	12.25 **Cybersecurity and Safety by design - complete journey walkthrough with use cases** **Jacek Walaszczyk,** Operational Life Sciences/ Industrial Control Systems security Senior Manager, **EY**
12.45 **Take control of Safety Letter Distribution through process automation** **Karin Van Doort,** Product Owner, **Pharmasol**	12.45 **Significance of adopting a risk based approach for conducting Pharmacovigilance audits, and gearing up for disruptive innovation**	12.45 **Transforming Beyond Compliance into a Safety Intelligence Organization** **Sharmila Sabaratnam,** Senior Director Vault Safety Strategy EU, **Veeva Systems**	12.45 **Compliance Intelligence – Driving force for Drug Safety Assurance: An Integrated QPPV oversight office perspective**	12.45 **PV Automation Beyond Efficiency: Journey From Objectives to Achieving Desired Outcomes** **Vladimir Penkrat,** Associate VP – Global	12.45 **Patient Safety Device & Digital Center of Excellence** **James Whitehead,** Patient Safety Medical Device Lead**, AstraZeneca**

	Marian Daryouzeh, Senior Manager in Life Sciences, **EY**		**Jay Dave,** Technical Director, Head of Global Pharmacovigilance, **COD Research**	Head of Safety & Reg Affairs, **Indegene**	

13.05 **Networking Lunch**

14.15 Roundtables

Roundtable 1 – Implementation of risk management and signaling in the MENA Region & comparisons with EU
Shahinaz Badr, Pharmacovigilance Consultant and PVQA Auditor – EMEA, **Pharma Quality Europe**

Roundtable 2 – Innovation for effective risk minimization activities
John Solomon, Head of Pharmacovigilance, UK and Ireland, **Sanofi** & **Yusuf Tanrikulu**, Deputy EU QPPV, **Roche**

Roundtable 3 – How might we improve risk management outcomes using perspectives from behavioral science?
Marie-Claire Wilson, Engagement Manager, **Axian Consulting**

Roundtable 4 – Safety business partnerships in the service of patients
Manni Kuthiala, PV Country Cluster Lead - LATAM, **Roche** & **Zuzana Kusynova**, Lead, Policy, Practice & Compliance, **International Pharmaceutical Federation** & **Lisa Miyasaki**, Vice President, Drug Safety & Pharmacovigilance, **Coherus Biosciences**

Roundtable 5 – Challenges and maintaining EU and local PSMFs
Laura Paolo Boga, Head of Global Pharmacovigilance, UK & EU QPPV, **Dompe Farmaceutici SPA** & **Marco Colombati,** Corporate Pharmacovigilance Compliance Specialist, **ITALFARMACO SP**

Roundtable 6 – Meeting the needs of multiple national QPPVs: does every company need a Global QPPV?
Sina Schader, EEA and UK QPPV, **AbbVie & Julia Appelskog**, Head of QPPV Office, **Novavax**

Roundtable 7 – How to get the best out of your safety vendors: sharing best practices
Amina Baljic, Head of PV Ops & PV Excellence, **Grunenthal Group** & **Luke Keitel**, Head of GCP/GVP Audit and Quality Risk Management, **Lundbeck**

Roundtable 8 – Equitable access to PV systems in low- and middle-income countries
Teodora Perger, Director, Deputy Head of Safety & PV, **ViiV Healthcare & Alex Bica**, Senior Director, Global Clinical Safety and Pharmacovigilance, Global R&D**, CSL Behring**

Roundtable 9 – Automation of PSMFs
Jolanda De Bruijne, Executive Director PV Compliance, Oversight & Process Excellence (COPE), Pharmacovigilance Operations, **Astellas** & **Patricia Harding**, Senior Advisor, Medicines Quality Organisation, **Eli Lilly & Co**

Roundtable 10 – Dealing with challenges in pharmacovigilance contracts
Dnyaneshwar Sanap, EU & UK QPPV, Head, Regional PV and Global Compliance Training, **Glenmark Pharmaceutics** & **Camilla Hammerum**, Vice President, Global Patient Safety, Neuroscience Therapeutic Area Head, **Ipsen**

Roundtable 11 – Implementing quality in pharmacovigilance systems: standard operating procedures (SOPs) for training
Sandra Reda, Quality Assurance Specialist & Deputy QPPV, **OnePharmaMedics & Ajibade Adesina**, Associate Director, PV Process Excellence and Learning Strategy, **Bristol Myers Squibb**

Roundtable 12 – Patient safety in the context of medical devices and new digital healthcare solutions
Katerina Sakkoula, Head of Affiliate Global Interface, **Roche & Feryal Tanriverdio,** Head of Patient safety and Pharmacovigilance Digital Innovation, **Boehringer Ingelheim**

Roundtable 13 – Pharmacovigilance and orphan drugs: managing risk and signals
Mahalakshmi Elluri, EU QPPV, **Amryt Pharma** & **Michael Dooley**, PV Manager and Deputy QPPV, **Amryt Pharma**

Roundtable 14 – Meeting local requirements in a global framework: navigating regulator expectations
Marie Pihl, Senior Director, PV Processes, Partnerships & Contracts, **AstraZeneca** & **Anna Karin Traff**, Director PS Operations, Technology & Analytics, **AstraZeneca**

Roundtable 15 – Safety implications of EFSA assessment of titanium dioxide on medications
Lambert Creuwels, Senior Medical Safety Adviser, Global Patient Safety, **Lundbeck**

Roundtable 16 – Cyber security – a strategic imperative for patient safety and data protection
Daniel Rüth, Partner and Head of Life Sciences Cyber Security EMEIA, **EY**

Roundtable 17 – Structured content authoring in PV for achieving greater efficiencies and consistency
Ranga Reddy, Global Head of Drug Safety Technologies, **Vifor Pharma**

Roundtable 18 – Moving beyond the safety database to answer regulatory questions
Nicola Wallis, Executive Director, PV Innovation, UK QPPV, **Beigene & Marcin Marciniak**, Senior Director, Global Safety and PV Expert WHC, **Gedeon Richter**

Roundtable 19 – Data science, AI and Machine Learning: the path to improved safety
Michael Braun-Boghos, Senior Director Safety Strategy, **Oracle Health Sciences**

Roundtable 20 – How Technology is Enabling Safety as a Strategic Partner
Sharmila Sabaratnam, Senior Directory Vault Safety Strategy EU, **Veeva Systems**

Roundtable 21 – Leveraging AI and Analytics to Unlock Strategic Insights and Make Sense of Big Data
Isabel Kloer, Lead, Risk Management Physician and Product Owner, **Boehringer Ingelheim & Emmanuel Belabe**, AVP, Solution Consulting, **ArisGlobal & Tims Thimmanna**, Associate Director, Product Management, **ArisGlobal**

AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**QUALITY ASSURANCE & COMPLIANCE**	**CASE PROCESSING**	**MEDICAL DEVICES**
15.10 **Chair: Andrea Maulwurf**, Head of Corporate Pharmacovigilance, Global Heading QPPV, **Allergy Therapeutics**	15.10 **Chair: Mark Perrott**, Managing Partner, **Axian Consulting Ltd**	15.10 **Chair: Vipin Sethi**, Head of Global Pharmacovigilance and Medical Affairs, **Cadila Pharmaceutical Limited**	15.10 **Chair: Katrien Soleme**, Senior Director, Pharmacovigilance and Life Cycle Management Quality, **Bristol Myers Squibb**	15.10 **Chair: Monika Kowalska**, Director, PV Operations ICSR Quality, **Moderna**	15.10 **Chair: Sylvie Bartus**, Senior Director, Clinical Safety Global, Clinical

					Affairs, Surgical Structural Heart, **Edwards Lifesciences**
15.15 **Bringing AI into case management activities** **Julie Girod**, Associate VP, Global Head of Case Management and Medical Evaluation, **Sanofi**	15.15 **What Does High Quality Digital Risk Minimization Look Like?** **Jane Feron**, Senior Director, Patient Safety Risk Management, **AstraZeneca**	15.15 **A cross-organisational monitoring system to overcome challenges brought by mass vaccination** **Lionel Van Holle**, Founder, **OpenSourcePV**	15.15 **PV Quality risk management: a risk-based approach for compliance** **Heike Von Treichel**, Head of PV QMS and Deputy QPPV, **Merck Healthcare**	15.15 **Setting up in-house clinical trial safety operations: overviews and metrics** **Katarzyna Gruchala**, Director, PV Operations Case Processing, **Moderna & Monika Kowalska**, Director, PV Operations ICSR Quality, **Moderna**	15.15 **Cross-functional efforts to meet EU-DAMED reporting requirements** **Sylvie Bartus**, Senior Director, Clinical Safety Global, Clinical Affairs, Surgical Structural Heart, **Edwards Lifesciences**
15.35 **How can we do better using AI? Use cases of medical literature monitoring.** **Nicole Baker,** CEO, **biologit**	15.35 **Applying behavioural science to risk minimization: An exploratory project** **Jeremy Jokinen**, Vice President, Global Risk Management & International Patient Safety, **Bristol Myers Squibb**	15.35 **Causality Assessment in the Context of Signal Detection** **Peter Nowicki,** Sr. Director of PV Products, Head of Innovation Lab, **RxLogix**	15.35 **COVIDRIVE: a public-private partnership to estimate brand-specific COVID-19 vaccine effectiveness in Europe.** **Kaatje Bollaerts,** Head of Data Science, **P95**	15.35 **Global ICSR: how to manage local languages** **Hans-Jörg Römming,** Head, Global Patient Safety Operations, **Merck Healthcare KGaA**	15.35 **Transforming Safety operating model for the future of integrated health solutions** **Amanda Bowles,** Managing Director, **Deloitte**
15.55 **Working through business cases for AI return on investment**	15.55 **A Digital Approach for Additional Risk Minimisation Activities**	15.55 **Challenges of signalling during the COVID pandemic**	15.55 **Mid-size pharma experiences in audits and inspections during the pandemic**		15.55 **Medical device regulation versus GVP risk management**

Anna Luk, Senior Director, Systems, Global Patient Safety, **Gilead Sciences**	**Wivina De Waele**, Director, EMEA, Global Drug Safety, **Alexion**	**Maria Maddalena Lino,** Safety Risk Lead Director, COVID Vaccine, **Pfizer**	**Gemma Jimenez Sese,** Corporate Drug Safety Head, EU QPPV, **Almirall**		**Lisa Benaise,** VP, Head of Pharmacovigilance, **Calliditas**
16.15 **Networking Break**					
AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**QUALITY ASSURANCE & COMPLIANCE**	**CASE PROCESSING**	**MEDICAL DEVICES**
16.45 **Chair: Claudia Lehmann**, VP, Head, Global Pharmacovigilance Operations & Systems, **Boehringer Ingelheim**	16.45 **Chair: Andrew Erdman**, Vice President, Global Head of Early Development Safety, Late Stage and Marketed Medicines Safety, **Genentech**	16.45 **Chair: Rudi Scheerlinck**, Safety Strategy Lead, **Merck Healthcare Oncology**	16.45 **Chair: Claudia Bäcker**, Head of Audit, Inspection, Deviation and CAPA Management, **Merck Healthcare**	**16.45 Chair: Fee Alexandra Gedlich**, Head of Local Patient Safety and Pharmacovigilance, Germany, **Boehringer Ingelheim**	**16.45 Chair: Milos Stojkovic**, Senior Safety Scientist, **Smith+Nephew**
16.50 **Automation and pharmacovigilance: identifying risk factors for AEs** **Michael von Forstner,** Head of Clinical Safety and Pharmacovigilance, Biosimilars, **Biogen**	16.50 **Update on PV in the Balkans** **Marjan Dzeparoski,** RA and PV Manager, **Bionika Pharmaceuticals**	16.50 **Diverse product profiles: detecting signals in a mid-sized company** **Fabian Heisig**, SVP Head Global Drug Safety & Qualified Person for Pharmacovigilance, **Grunenthal Group**	16.50 **Pharmacovigilance compliance and governance in challenging scenarios** **Eva van Engelen**, Director, Global Patient Safety, **Gilead Sciences**	16.50 **Standing up Safety –practical guidance for startups** **Christopher Flood**, Senior Director, Safety Operations, **Erasca Inc**	16.50 **Safety in PMCF medical device studies: challenges and updates** **Talia Milosevic**, Senior Manager, Clinical Safety, Surgical Structural Heat, **Edwards Lifesciences**
17.10 **Next Gen Safety in Production: How End-to-**	17.10 **Risk Management Plan**	17.10 **New strategies in signal detection: usage of probabilistic tools**	17.10 **Making your PSMF global: a practical case study**		17.10 **Global trends in RWE for medical de-**

End Automation and Analytics are Shaping Safety **Emmanuel Belabe**, AVP, Solution Consulting, **ArisGlobal**	**Vjera Bilušić Vundać**, Director of Medical Writing, **PrimeVigilance**	**Fabio De Gregorio**, Vice President, Head of Drug Safety Europe, **Shionogi Europe**	**Delphine Bertram,** Head, Safety Vigilance, EMEA Operations, EU QPPV, **Santen**		**vice regulatory submission: an evolving landscape** **Shweta Agarwal,** Manager, MedTech and Life Sciences, **EY** & **Claire Fielder**, Enterprise Risk Consulting Senior, **EY**
17.30 **Next generation safety through current generation AI/ML** **Andrew Bate**, VP & Head, Safety Innovation & Analytics, Global Safety, **GSK**	17.30 **Global risk management strategies: ensuring patient safety worldwide** **Alina Tudor,** Senior Director, Pharmacovigilance, **Kyowa Kirin International**				

17.50 **Close of conference and drinks reception**

Day 2 – Wednesday 28th September 2022

08.55 **Chair's remarks**

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

Morning Plenary

09.00 **Innovations in Patient Care & Advocacy – How the Medical Devices Industry Has Adapted to Meet Patient Needs During the Pandemic**
Jijo James, Chief Medical Officer, Medical Devices**, Johnson & Johnson**

09.20 **Practical experiences in Chinese PV Regulation and GVP Implementation**
Gloria Bustos, Senior Director, Head of Pharmacovigilance, EMEA & APAC / Global Patient Safety**, Baxter Healthcare**

09.40 **The Future Is Now: Advancing Patient Safety through Innovations in Data and Analytics**
Aman Wasan, Chief Commercial Officer, **ArisGlobal**

10.00 **Automation and machine learning in PV: over promising or under-delivering?**
Jens-Ulrich Stegmann, Senior Vice President, Head Clinical Safety and Pharmacovigilance, EU QPPV**, GSK**

10.20 **Panel Discussion: The nature of corporate vs regulator responsibility in keeping patients safe**
Chair: Jens-Ulrich Stegmann, Senior Vice President, Head Clinical Safety and Pharmacovigilance, EU QPPV**, GSK**
Shinobu Uzu, Senior Executive Director, **Pharmaceuticals and Medical Devices Agency, Japan**
Fatima Bhayat, Vice President, Head of Global Patient Safety and Chief Safety Officer, **Amgen**
Phil Tregunno, Group Manager, Vigilance, Intelligence and Research**, Medicines & Healthcare Products Regulatory Agency**
Jean-Christophe Delumeau, Board Director, **Institute of Pharmacovigilance**

Marti Hrvoje table 4 11:00 Karolina Biomapas t. 5 11:20

11.00 **Morning Break**

Track 1	Track 2	Track 3	Track 4	Track 5	Track 6

AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**QUALITY ASSURANCE & COMPLIANCE**	**CASE PROCESSING**	**DIGITAL TRANSFORMATION**
11.40 **Chair: Mircea Ciuca**, Global Therapeutic Area Head, Global Clinical Safety & PV, **CSL Behring**	11.40 **Chair: Marija Briede,** Head of Pharmacovigilance, QPPV, **Grindeks**	11.40 **Chair: Sutirtha Mukhopadhyay**, Senior Patient Safety Physician, **Boehringer Ingelheim**	11.40 **Chair: Wasim Anwar**, Vice President & Deputy QPPV, Global Safety, **Novo Nordisk**	11.40 **Chair: Roberta Amodeo**, Associate Director, ECP Regional Management, **Biogen**	11.40 **Chair: Peter De Veene**, QPPV, **Incyte Biosciences**
11.45 **Emerging digital sources of safety information** **Hadir Rostom**, President, **ISoP Egypt Chapter** and **Lecturer**, Faculty of Pharmacy, **Modern Sciences and Arts University**	11.45 **Characterizing the safety profile of HSC gene therapies** **Mattia Calissano,** Head of Drug Safety and Risk Management & Italy & UK QPPV**, Orchard Therapeutics**	11.45 **Early detection of signals in rare diseases** **Sutirtha Mukhopadhyay**, Senior Patient Safety Physician, **Boehringer Ingelheim**	11.45 **Remote inspections and varying approaches: adapting to the new normal** **Lucy Hampshire**, Associate Vice President, Head, Medicines Quality Organisation International, **Eli Lilly & Co**	11.45 **Building quality and inspection readiness into your PV operations** **Jennifer Kane**, Senior Director, Pharmacovigilance Operations & Compliance, **Arcus Biosciences**	11.45 **Applied Data Science in Modern Pharmacovigilance** **John Reinhard Pietzsch**, Head of Data Science & Insights, **Bayer**
12.05 **Case Processing – The Most Important Part of Pharmacovigilance – So Manual or Automated for the future?** **Graeme Ladds,** Director of Pharmacovigilance/CEO, **PharSafer**	12.05 **Target Safety Margin Tool for Early Safety Assessment** **Catherine Noban,** Lead Product Manager Biology Solutions, **Elsevier**	12.05 **Advanced methodologies for signal detection in COVID-19 Vaccines** **Robert Weber** Product Management Director, **Oracle Health Sciences**	12.05 **Securing PV compliance while outsourcing: challenges and opportunities – A quality assurance perspective** **Magda Daudin**, Director, Pharmacovigilance QA Lead, **Idorsia**	12.05 **EU Clinical Trials Regulation: Implementation of RSI Effectiveness for ICSR Expectedness Assessments** **Maritess Esguerra,** Senior PV Process	12.05 **Using digital technologies to inform risk minimization effectiveness** **Jeremy Jokinen**, Vice President, Global Risk Management & International Patient Safety, **Bristol Myers Squibb**

				Director, **Genentech & Ayesha Bailey**, IT Business Partner, **Roche**	
12.25 **Leveraging data science for predicting risks within PV systems** **Minhaj Obediullah**, Head, Compliance and Risk Management, **Novartis**	12.25 **Strategic approaches to evaluating the benefit risk profile of medicines** **Tjark Reblin**, Global Head Drug Safety and Risk Management, **Vifor Pharma**	12.25 **Ensuring alignment with local signal management regulations** **Annemette Boye**, Deputy QPPV, **Seagen**		12.25 **A holistic approach towards a Life Sciences Quality Value Network** **Christian Schmitz-Moormann,** Life Sciences Facilitator, **Generis**	
	12.45 **Implementation of Educational Materials on a national level in the European Union (EU). Country Differences, challenges and best practices.** **Martynas Juzenas,** COO, **Insuvia**	12.45 **On Demand Signal Refinement and Validation with Real World Data** **Robert Kyle,** Vice President, **TriNetX**			
13.05 **Networking Lunch**					
14.15 **Roundtables** **Roundtable 1 - Improving the under reporting of adverse events within de-centralised trials** **Vivienne van de Walle**, Medical Director, **Precare Trial and Recruitment Research Centre**					

Roundtable 2 - Operating models of local PV systems in country organisations: challenges and experiences
Attila Olah, Head Global Patient Safety, EU/UK-QPPV, **Gedeon Richter & Vipin Sethi**, Head of Global Pharmacovigilance and Medical Affairs, **Cadila Pharmaceutical Limited & Albert Befki**, Head of Pharmacovigilance Operations, **Biomapas**

Roundtable 3 - Integration of pharmacovigilance systems in the EU: challenges and opportunities
Marco Colombati, Corporate Pharmacovigilance Compliance Specialist, **ITALFARMACO SPA & Tommaso Venturi**, Corporate Pharmacovigilance Risk Assessment Specialist, **ITALFARMACO SPA**

Roundtable 4 - Modular approaches to PSMFs
Monika Manske, Lead Quality Management and Deputy EEA QPPV, **Viatris & Klaus Bitsch-Jensen**, Deputy QPPV, **ALK & Adriana Radu**, Head, Drug Safety Evaluation & QPPV, **Mundipharma**

Roundtable 5 – Streamlining PV system compliance metrics: how to keep QPPV oversight and improve accuracy?
Jan Cleerbout, Deputy EU QPPV, QPPV Office, **Johnson & Johnson** & **Magnus Ysander**, EU & UK QPPV & Head, Pharmacovigilance Excellence, **AstraZeneca & Alexion**

Roundtable 6 – Differences between local pharmacovigilance activities: between EU and non-EU countries
Tatjana Ajhler Duretek, Head of Medical Affairs and Pharmacovigilance, EU QPPV, **Belupo Pharmaceuticals & Cosmetics & Samah Ragab**, Director, Regulatory Affairs & PV, Middle East, **Organon**

Roundtable 7 – Remote audits and inspections: challenges and lessons learned
Mijal Chavda, Director, Global GxP Inspections & GVP Quality, **Kyowa Kirin** & **Clara Goncalves**, Head QPPV & Alliance Office, **Grunenthal Group**

Roundtable 8 – New expectations from GVP XVI
Klaudija Marijanovic Barac, Senior Director, Global Patients Safety & PV – TPC, **Teva Pharmaceuticals**

Roundtable 9 – QPPV oversight of safety databases
Raphael Van Eemeren, Director, EU/UK QPPV, **Amgen**

Roundtable 10 – Challenges in creating a compliance environment within and outside of your safety organisation
Ketan Marulkar, Senior Pharmacovigilance Officer, Deputy QPPV, **Chanelle Pharma**

Roundtable 11 – Probabilistic tools for causality assessment and signal detection
Fabio De Gregorio, VP, Head of Drug Safety Europe, **Shionogi Europe** & **Rachel McDermott**, Drug Safety Physician, **Shionogi Europe**

Roundtable 12 – Post-marketing surveillance of COVID-19 vaccines: regulatory requirements & managing high volumes
Antonella Fretta, Senior Director, Aggregate Reporting Team Lead, **Pfizer** & **Marcin Kruk**, Senior Director, Drug Safety Unit Regional Head, Europe, Africa & Middle East, **Pfizer**

Roundtable 13 – Medical Device Postapproval Safety Monitoring, Postmarketing safety reporting: using RWE to drive Medical Device innovation
Alexandros Charitou, Associate Partner, **EY**

Roundtable 14 – Interconnection of safety, quality and compliance in advanced cell therapy: experiences from small biotech
Jessica Chinault-Jalboot, Head of Quality & Compliance, GCP/GVP & Regulatory, **AlloVir** & **Dany Ward**, Senior Director, Clinical Safety & Risk Management, **AlloVir**

Roundtable 15 – When to improve the now and when to improve the future: automation in drug safety
Mark Widdowson, Manager, Digital Insights and Innovation, **Bristol Myers Squibb**

Roundtable 16 – The current international medical device safety landscape: regulation evolutions
Omar Aimer, Lead, Medical Device Safety, Special Interest Group, **ISoP**

Roundtable 17 – Specific safety considerations for paediatric patients
Sabine Fuerst-Recktenwald, Principal Medical Director Personalized Health Care (PHC) Safety, **Roche**

Roundtable 18 - "Add-ons or Go Native" A systems integrators' POV on Bolt-ons or One Platform to Rule it All
Chris Jabbal, Senior Vice President & **Anjani Jha,** President and C.E.O., **Nextrove**

Roundtable 19 – Patient perspectives and minding the gap: where and how do patients and industry meet
Mary Lynne Van Poelgeest-Pomfret, President, **World Federation for Incontinence and Pelvic Pain (WFIPP) & Panagiota Diamantopoulou Reiter**, Senior Director, Safety Physician, **Genmab**

Roundtable 20 – Union of NLP and DA: Gold Standard for Causality assessment – Gerardi to Garmin to Google – A futuristic look
Sanjeev Srivastav, Team Lead: Signal and PSR, **ProPharma**

AI + AUTOMATION	RISK MANAGEMENT	SIGNAL DETECTION & MANAGEMENT	QUALITY ASSURANCE & COMPLIANCE	CASE PROCESSING	DIGITAL TRANSFORMATION
15.10 **Chair: Israel Gutierrez**, VP, Drug Safety and Pharmacovigilance, **Compugen**	15.10 **Chair: Manni Kuthiala**, PV Country Cluster Lead - LATAM, **Roche**	15.10 **Chair: Asif Mahmood**, Chief Safety Officer, Global Clinical Safety & Pharmacovigilance, **Medicago**	15.10 **Chair: Ricarda Tiemeyer**, Head of Pharmacovigilance, DACH Region, **Biogen**	15.10 **Chair: Peter Kohut**, Pharmacovigilance Lead, **Alvotech**	**15.10 Chair: Hans-Jörg Römming,** Head, Global Patient Safety Operations, **Merck Healthcare KGaA**
15.15 **IMI ConcePTION app: safety information exchange for pregnancy and breastfeeding** **Amalia Alexe**, PV Office and Liaison Lead, QPPV, PRRC Office, **Novartis**	15.15 **IMI PREFER project: why, when and how to include patient preference in the medical products decision making** **Juhaeri Juhaeri,** VP & Head, Epidemiology and Benefit-Risk, **Sanofi**	15.15 **Defining the UK Policy and Strategy in Medicine Safety** **Belen Granell Villen**, Quality and Safety Policy Executive, **The Association of the British Pharmaceutical Industry**	15.15 **PV systems considerations in mergers and acquisitions** **Gabrielle Amselem**, Director, PV Excellence Expert, **Alexion, AstraZeneca Rare Disease**	15.15 **Effective Pharmacovigilance System Development: EFPIA-IPVG Consensus Recommendations** **Tanja Peters**, Head, Global Patient Safety, Neurology & Immunology, Fertility, **Merck Healthcare KGaA**	15.15 **Lessons learned from using artificial intelligence to detect adverse reactions** **Adrian Maynier**, Head of Safety Systems, **UCB**
15.35 **Breaking down the barriers for successful innovation implementation** **Sibel Guerler**, Head of Innovation, Partnerships and Process Optimisation, WorldWide	15.35 **Health authorities and risk management: core global RMPs** **Veronica Urdaneta**, Senior Director, Global Safety Physician, Pharmacovigilance, **Moderna**	15.35 **Responding to an urgent need: immunodepression and COVID-19** **Alejandra Padovani**, Safety Director, **Roche**	15.35 **PV system compliance activities related to data collection through organised patient systems: control and oversight**	15.35 **Pharmacovigilance in gene therapy** **Ashlyn Bassiri**, VP of Immunology, **Kriya Therapeutics**	15.35 **Transforming data into decisions** **Andrew Rut,** Senior Executive, **Qinecsa Solutions**

Patient Safety, **Bristol Myers Squibb**			**Clémence Elie**, VP, Head of Global Patient Safety, dQPPV, **Ipsen**		
					15.55 **Data collection and patient safety: communicating adverse events** **Chinmaya Mahapatra,** Founder & President, **Global Pharmacovigilance Society** & Pharmacovigilance Associate, **Indian Pharmacopeia Commission**
16.15 **Networking Break**					
AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**QUALITY ASSURANCE & COMPLIANCE**	**CASE PROCESSING**	**DIGITAL TRANSFORMATION**
16.45 **Chair: Dennis Vargo**, VP, Head of Drug Safety and Pharmacovigilance, **Akebia Therapeutics**	16.45 **Chair: Wivina De Waele**, Director, EMEA, Global Drug Safety, **Alexion**	16.45 **Chair:**	16.45 **Chair: Jutta Syha**, Independent Consultant	16.45 **Chair: Signe Nielsen**, Manager of Safety Operations, **ALK**	16.45 **Chair: Pilar Carrero**, Vice President, Global Safety, **LEO Pharma**
16.50 **Automation solutions for pharmacovigilance in Ukraine and post-Soviet Union countries**	16.50 **Advances in benefit-risk evaluation: from regulatory to industry perspectives**	16.50 **DHPC: a well-oiled machine** **Sina Schader**, EEA and UK QPPV, **AbbVie**	16.50 **PV QA: PV Personnel expectations in MENA region** **Mina G Awad,** Pharmacovigilance Manager and QPPV,	16.50 **Pharmacovigilance agreements: supporting case processing requirements with our partnerships**	16.50 **Applying textmining for latency determination**

Dmytro Horilyk, CEO, **DrugCards** & **Olena Matveeva, Manager**, Pharmacovigilance Quality & Technical Officer for Pharmacovigilance, **Acino Pharma & WHO**	**Stephanie Tcherny-Lessenot**, Head of Benefit-Risk Evaluation, **Sanofi**		Middle East, **Kyowa Kirin International**	**Valentina Mancini,** Senior Director, Pharmacovigilance, QPPV, **Shionogi Europe & TransCelerate**	**Wei Wannhoff**, Safety Data Analyst, Global Patient Safety, **Merck Healthcare KGaA**
17.10 **Innovation in pharmacovigilance: everybody's business** **Vivek Ahuja**, Vice President – Medical Affairs & Head, Global Pharmacovigilance, **Sun Pharmaceuticals**	17.10 **Pragmatic and large simple trials in benefit risk assessment** **Claudia Ana Ianos**, Senior Director, Safety Risk Lead, **Pfizer**	17.10 **Moving beyond the safety database in serving our customers** **Nicola Wallis**, Executive Director, PV Innovation, UK QPPV, **Beigene**	17.10 **How to establish worldwide trustful and reliable partnerships for PV systems** **Jutta Syha**, Independent Consultant		17.10 **Local implementation of a digital case intake tool** **Ariane Stollenwerk**, Safety Leader, Germany, Austria and Switzerland, **UCB**

17.30 **Close of conference**

Day 3 – Thursday 29th September 2022

08.55 **Chair's remarks**

Morning Plenary

09.00 **AI in signal detection: social media listening for COVID-19 vaccines**
Juhaeri Juhaeri, VP & Head, Epidemiology and Benefit-Risk, **Sanofi**

09.20 **Benefit, risk and safety profiles of novel plant-based vaccines**
Asif Mahmood, Chief Safety Officer, Global Clinical Safety & Pharmacovigilance, **Medicago**

09.40 **What next for signal detection and management?**
Fatima Bhayat, Vice President, Head of Global Patient Safety and Chief Safety Officer, **Amgen**

10.00 **Morning Break**

Track 1	**Track 2**	**Track 3**	**Track 4**	**Track 5**	**Track 6**
AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**QUALITY ASSURANCE & COMPLIANCE**	**EMERGING MARKETS**	**PV OUTSOURCING**
11.00 **Chair: Pav Rishiraj**, Director, Head of Patient Safety, **Ipsen** & PV Expert Chair, **ABPI**	11.00 **Chair: Mette Stie Kallesoee**, Deputy QPPV, **Leo Pharma**	11.00 **Chair: Rita Lobatto,** Senior Director, Pharmacovigilance, Deputy QPPV, **Pharming Group**	11.00 **Chair: Jeremie Dedessus Le Moutier,** Head of Global PV Excellence, Global Safety, **GSK**	11.00 **Chair: Shahinaz Badr**, Pharmacovigilance Consultant and PVQA Auditor, EMEA, **Pharma Quality Europe**	11.00 **Chair: Tommaso Venturi**, Corporate Pharmacovigilance Risk Assessment Specialist, **ITALFARMACO SPA**
11.05 **Artificial intelligence – future for pharmacovigilance and drug safety professionals**	11.05 **Clinical risk management: pharmacovigilance in clinical practice for medical doctors**	11.05 **Embedding signal management in PV processes: proper action and common sense** **Bert Van Leeuwen,** Deputy QPPV, **Astellas**	11.05 **Global Process owner: an end-to-end accountability towards a critical path to cross-functional process management**	11.05 **Effective PV systems: harmonisation in emerging markets**	11.05 **How to get the best out of outsourcing** **Abiola David**, Director, Medical Information, Safety Services & Vendor Management, **GSK**

Vipin Sethi, Head of Global Pharmacovigilance and Medical Affairs, **Cadila Pharma**	**Galina Cordero**, Head of Pharmacovigilance Department, QPPV, **JSC Farmak Ukraine**		**Jeremie Dedessus Le Moutier**, Head of Global PV Excellence, Global Safety, **GSK**	**Willemijn van der Spuij,** Executive Director, Worldwide Patient Safety International, **Bristol Myer Squibb**	
	11.25 **Risks through drug development: easy to get into but hard to get out of** **Max Waschbusch**, TA Head Cardiovascular and Metabolism, **CSL Behring**	11.25 **I spy with LASIE** **Vivien Stettner**, Regional PV Director, WEC, International PV Op Excellence, **AbbVie**	11.25 **Globalising PV compliance** **Joel Johansen**, Vice President, Global Head of PV Compliance and PV Head EMEA, **Kyowa Kirin International**	11.25 **Strategies and approaches implemented by SAHPRA to improve pharmacovigilance in South Africa during the COVID-19 pandemic** **Mafora Florah Matlala**, Vigilance Manager, **South African Health Products Regulatory Authority (SAHPRA)**	11.25 **Challenges in working with CROs in pharmacovigilance** **Riti Shah**, Medical Director, Pharmacovigilance, **Chiesi USA**
12.00 **Networking Lunch**					
13.00 **Roundtables** **Roundtable 1 – Patient engagement as a future trend: a collaborative approach** **Jessica Hansen**, Patient Engagement Manager, **Bayer** & **Sarah Al-Musaed**, Regulatory Affairs and Drug Safety Specialist, **Grunenthal Group** **Roundtable 2 – Navigating the Brexit landscape: where are we now?**					

Pav Rishiraj, Director, Head of Patient Safety, **Ipsen** & PV Expert Chair, **ABPI**

Roundtable 3 – Monitoring the impact of global regulatory strengthening
Jean-Christophe Delumeau, Board Director, **Institute of Pharmacovigilance & Sean Burke**, Senior Director, Regional Lead, International Pharmacovigilance, **MSD**

Roundtable 4 – Real world evidence enabled pharmacovigilance for COVID-19 vaccines and beyond
David Martin, Vice-President, Clinical Safety and Risk Management, **Moderna** & **Marie Pierre Caby**, EEA/UK QPPV, **Moderna**

Roundtable 5 – Patient safety: one vision, one networked community
Nikolas Minder, Scientific Business Director, **Roche** & **Margarita Zhelyazkova**, Global Pharmacovigilance and Compliance Specialist, **Independent**

Roundtable 6 – Remote vs onsite inspections: challenges and opportunities
Tea Babic, Director, Audits and Inspections, **Teva Pharmaceuticals** & **Mette Stie Kallesoee**, Deputy QPPV, **Leo Pharma**

Roundtable 7 – The new business model: outsourcing local PV activities
Lynne Comiskey, QPPV Compliance and Program Manager, **Sanofi** & **Cristina Vara Navarette**, European Pharmacovigilance Manager & Local Safety Officer for Germany and Austria, **Seagen**

Roundtable 8 - The role of Economic Operators under MDR. How to deal with possible overlapping of EO obligations?
Daniela Gramaglia, Medical Device Vigilance Manager, **Chiesi Farmaceutici**

Roundtable 9 – Working with a global PV vendor: best practices and future trends
Nicole Avalos, Director, Global Clinical Safety & Pharmacovigilance, Head of Safety Sciences, Reporting & Analytics, **CSL Behring** & **Linda Helmfors**, QPPV & Head of Pharmacovigilance, **Bluefish Pharmaceuticals**

Roundtable 10 – Providing equitable access to safe and effective vaccines
James Milligan, **Independent PV Expert**

Roundtable 11 – Experience and challenges with EU clinical trials regulation (CTR) implementation
Maritess Esguerra, Senior PV Process Director, **Genentech & Ayesha Bailey**, IT Business Partner, **Roche**

Roundtable 12 – Drug safety assessment in pregnancy
Diego Wyszynski, CEO & Founder, **Pregistry**

TRANSLATIONAL SAFETY	**VACCINE SAFETY**	**PATIENT ADVOCACY**	**SAFETY IN ONCOLOGY**	**PV OUTSOURCING**
14.00 **Chair:** **Sabine Fuerst-Recktenwald**, Principal Medical Director Personalized Health Care (PHC) Safety, **Roche**	14.00 **Chair:** **Frédérique Delannois**, Director, Safety evaluation & Risk Management Team Leader, Global Safety, **GSK**	14.00 **Chair:** **Yvonne Nanciu**, Head of Pharmacovigilance Germany, **Bayer**	14.00 **Chair:** **Stewart Geary,** Global Safety Officer & Senior Vice President, **Eisai**	14.00 **Chair: Riti Shah**, Medical Director, Pharmacovigilance, **Chiesi USA**
14:05 **Human organs physiology and engineering: for closing the pre-clinical gap** **Annie Moisan,** Program Director, HOPE, **Wellcome Leap**	14:05 **Meeting the international pharmacovigilance regulatory requirements for the COVID-19 vaccine** **Emmanuelle Pines**, Head of Safety Policy & Process Oversight, QPPV Office, **Janssen**	14:05 **Making the patient's perspectives work** **Jacquelien Noordhoek,** President**, CF Europe**	14:05 **PV in expanded and compassionate use for oncology** **James Eldridge**, Director, Pharmacovigilance North America, **Y-mAbs**	14:05 **The importance of vendor oversight** **Theresa Markey**, Director and Head, Safety Operations, **Corcept Therapeutics**
14.25 **Patient derived tissue models to support personalised safety** **Adrian Roth**, Principal Scientific Director, Personalised Health Care Safety, **Roche**	14.25 **HPV-vaccination and ceramic skin patches** **Mike de Leeuw**, CEO, **My Life Technologies**	14.25 **Giving purpose to our pain: building a community through collaboration** **Christine Von Raesfeld,** Founder, & CEO, **People with Empathy**	14.25 **The role of real world evidence in safety** **Tanuja Halady**, Head of GPS Oncology Group III, Medical Safety Global Patient Safety, **Merck**	

14.45 **Close of conference**