World Drug Safety Europe Congress 2021

6-7th October 2021 – Hilton Amsterdam

Speakers Confirmed for 2021

1. **Felix Arellano,** Global Head of Pharmacovigilance and Drug Safety**, Roche**
2. **Mariette Boerstoel Streefland,** SVP Patient Safety, Chief Safety Officer**, AstraZeneca**
3. **Sumit Munjal,** Vice President, EU QPPV and UK QPPV**, Takeda Pharmaceuticals & Vaccine**
4. **Simon Sinclair,** Chief Safety Officer**, Reckitt Benckiser**
5. **Tjark Reblin,** Global Head Drug Safety and Risk Management**, Vifor Pharma**
6. **Howard Snow,** Head Patient Safety Sandoz BioPharma & Generics, Novartis CMO & Patient Safety**, Novartis**
7. **Rishi Chopra,** Head of International Pharmacovigilance, Deputy EU QPPV & Deputy UK QPPV, **Biogen**
8. **Salvatore Cicirello,** Senior Director, Safety Science and PASS**, Celgene, a BMS company**
9. **Jan Cleerbout,** Deputy EU QPPV Pharma, PV System Oversight**, Johnson & Johnson**
10. **Khaudeja Bano,** Executive Medical Director, Combination Product Safety Head**, Amgen**
11. **Deanna Montes de Oca,** Global Head of PV Case Management**, Moderna**
12. **Sharon Fabrizio,** Head of Local PV Quality Oversight - Global Scope**, Sanofi**
13. **Phil Tregunno,** Group Manager, Vigilance, Intelligence and Research**, Medicines & Healthcare Products Regulatory Agency**
14. **Deepa Venkataraman,** Head of Global Patient Safety and Pharmacovigilance, **Summit Therapeutics**
15. **Christina Bisschops-Kaltenbach,** Global Head International Pharmacovigilance, Safety Risk Management**, Roche**
16. **Heike von Treichel,** Head of PV QMS and QPPV Office, Deputy European Qualified Person for Pharmacovigilance (Deputy EEA QPPV)**, Merck Healthcare**
17. **Adrian Maynier,** Head of Safety Systems, **UCB**
18. **Gloria Bustos,** Head of PV EMEA & APAC / Global Patient Safety**, Baxter Healthcare**
19. **Vipin Sethi,** Global Pharmacovigilance Head**, Cadila Pharmaceuticals**

20. **Laura Paola Boga,** Head of Global Pharmacovigilance & EU Qualified Person for Pharmacovigilance**, Dompé farmaceutici S.p.A.**
21. **Scott Chandler,** Global Head, Personalized Health Care (PHC) Safety, Product Development Safety**, Roche**
22. **Elian Khazneh,** Head of Medical Safety Operations**, Merck Healthcare**
23. **Rudi Scheerlinck,** Pharmacovigilance Risk Management Clinical Studies**, Galderma**
24. **Katrien Soleme,** Senior Director, Pharmacovigilance and Life Cycle Management Quality**, Bristol Myers Squibb**
25. **Uwe Gudat,** Head of Clinical Safety and Pharmacovigilance Clinical Safety and Pharmacovigilance**, Fresenius Kabi SwissBioSim**
26. **Valentina Mancini,** Director Pharmacovigilance, EU QPPV**, Shionogi Europe**
27. **Albert Bekfi,** Head of Pharmacovigilance Operations**, Biomapas**
28. **Anupam Agarwal,** Vice President, Global Head of Drug Safety and PV**, Zogenix**
29. **Ellen Ravn Englev,** Senior Director, Case Management department, Safety Operations, Global Safety**, Novo Nordisk**
30. **Mircea Ciuca,** Therapeutic Area Head Global Clinical Drug Safety**, CSL Behring**
31. **Daniela Di Cosmo,** Senior Pharmacovigilance Manager, Global Pharmacovigilance**, Ferring**
32. **Dennis Vargo,** Vice President, Head of Drug Safety and Pharmacovigilance**, Akebia Therapeutics Inc.**
33. **Phillip Eichorn,** Senior Director (Worldwide Safety and Regulatory)**, Pfizer**
34. **James Whitehead,** Patient Safety Medical Device Lead, **AstraZeneca**
35. **Eva van Engelen,** Associate Director, Global Patient Safety**, Gilead Sciences**
36. **Israel Gutierrez,** VP, Pharmacovigilance and Drug Safety**, Geron Corporation**
37. **Pav Rishiraj**, UK QPPV, Head of Patient Safety – UK and Ireland, **Merck Serono and,** PV Expert Chair, **ABPI**
38. **Liana Gross Martirosyan,** Alternate Member**, EMA - Pharmacovigilance Risk Assessment Committee**
39. **Monika Manske,** Lead Quality Management and Deputy EEA QPPV, PSRM, Pharmacovigilance Safety & Risk Management**, Viatris**

40. **Ranjana Khanna,** Director, Head Of PV, Quality Assurance**, Vifor pharma**
41. **Markus Krupp,** Associate Director, Safety Signal Management & Data Analytics**, Merck Healthcare**
42. **Sylvie Bartus,** Head of Clinical Safety, Surgical Structural Heart**, Edwards Lifesciences**
43. **Irene Morillo Alonso,** Clinical Assessor**, Spanish Agency of Medicines and Medical Devices**
44. **Melanie Dullemond,** Global Compliance Head, PV Quality – MCQO**, Sanofi**
45. **Amgad Shebl,** Director, Global Clinical Safety and Pharmacovigilance**, CSL Behring**
46. **Attila Olah,** Head Global Pharmacovigilance, Eu-Qppv**, Gedeon Richter**
47. **Lionel Van Holle,** Safety Surveillance Lead**, UCB and** Founder, **OpenSourcePV**
48. **Saeed Amin**, Vice President, Strategy, **Drogevate**
49. **Paolo Voltolina,** Director, Head of Regulatory Business Operations**, Lundbeck**
50. **Dragana Bundalo**, Regulatory Affairs Associate, **PharmaSwiss**
51. **Estelle Marrer-Berger,** Toxicology Project Leader**, Roche**
52. **Carmela Campana,** Deputy EU QPPV**, Istituto Biochimico Italiano G. Lorenzini**
53. **Céline Adessi,** Senior Director, Group Head, Oncology, Clinical Safety Science, **Roche**
54. **John Solomon,** Head of Pharmacovigilance [UK & Ireland]**, Sanofi**
55. **Andrea Maulwurf,** Head of Corporate Pharmacovigilance, Global Leading Qppv**, Allergy Therapeutics**
56. **Sutirtha Mukhopadhyay,** Senior Risk Management Physician**, Boehringer Ingelheim**
57. **Syed Zaferuddin,** Global Pharmacovigilance Manager and QPPV**, Julphar**
58. **Tarik Messaoud,** Drug Safety Physician**, Independent**
59. **Magda Daudin,** Director, Pharmacovigilance QA Lead**, Idorsia**

60. **Colleen Moody,** Senior Manager, Safety Risk Management Scientist**, United Therapeutics**
61. **Andrea Oliva,** Head of Pharmacovigilance, Italy, Product Safety & Risk Management**, Viatris**
62. **Talia Milosevic,** Manager, Clinical Safety, Surgical Structural Heart**, Edwards Lifesciences**
63. **Raj Long,** Deputy Director, Integrated Development, Global Health, **Bill and Melinda Gates Foundation**
64. **Siva Kumar Buddha,** Global safety Physician Manager, Product safety and Risk Management**, Viatris**
65. **Marjan Dzeparoski,** RA and PV Manager**, Bionika Pharmaceuticals**
66. **Muhammad Ashar Naeem,** Global Director Pharmacovigilance and Medical Affair**, Jamjoom Pharma**
67. **Ann Chivers,** Chief Executive**, Alström Syndrome UK**
68. **Omar Aimer,** Pharmacovigilance Specialist**, Brunel Canada/Sanofi**
69. **Mina Awad,** Pharmacovigilance Manager and QPPV, Middle East**, Kyowa Kirin International**
70. **Fatima Ghethan,** Head of Quality and Medication Safety Unit**, King Abdullah Medical City (KAMC)**
71. **Kristof Vanfraechem**, Founder and CEO, **Data For Patients**
72. **Belen Granell Villen,** Quality and Safety Policy Executive**, The Association of the British Pharmaceutical Industry**
73. **Hadir Rostom,** President**, ISoP Egypt Chapter and** Lecturer**,** Faculty of Pharmacy**, Modern Sciences and Arts University**
74. **Nibedita Rath,** Scientific Director**, Open Source Pharma Foundation**
75. **Mary Lynne Van Poelgeest-Pomfret,** President**, World Federation for Incontinence and Pelvic Pain – WFIPP**
76. **Sheila Khawaja,** Vice Chair**, WAPO**
77. **Vivienne van de Walle,** Medical Director**, Precare Trial and Recruitment Research Centre**
78. **Loubna Alj,** Pharmacist & Epidemiologist**, Public Health Centre Anti Poison et de Pharmacovigilance du Maroc**
79. **Alaa Yousef Ghidan,** Doctor, **The Higher Council for Science and Technology**

80. **Mark Perrott,** Managing Partner, **Axian Consulting Ltd**
81. **Jacquelien Noordhoek**, President**, CF Europe**
82. **Nicole Baker,** CEO**, biologit**
83. **Bruno Ohana,** CTO**, biologit**

Day 1 – Wednesday 6th October 2021

Morning Plenary

08.55 **Chair's remarks**
Felix Arellano, Global Head of Pharmacovigilance and Drug Safety**, Roche**

09.00 **Title Sponsor(Reserved for ORACLE)**

09.20 **Keynote Panel Discussion: Is it time to revisit our traditional approach to safety data gathering pre- and post-approval?**
Chair: Felix Arellano, Global Head of Pharmacovigilance and Drug Safety**, Roche**
Khaudeja Bano, Executive Medical Director, Combination Product Safety Head**, Amgen**
Liana Gross Martirosyan, Alternate Member**, EMA - Pharmacovigilance Risk Assessment Committee**
Deepa Venkataraman, Head of Global Patient Safety and Pharmacovigilance, **Summit Therapeutics**
Raj Long, Deputy Director, Integrated Development, Global Health, **Bill and Melinda Gates Foundation**
Phil Tregunno, Group Manager, Vigilance, Intelligence and Research**, Medicines & Healthcare Products Regulatory Agency**
Sumit Munjal, Vice President, EU QPPV and UK QPPV**, Takeda Pharmaceuticals & Vaccines**

10.20 **Morning Break**

Track 1	**Track 2**	**Track 3**	**Track 4**
AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**QUALITY ASSURANCE AND COMPLIANCE**
11.20 **Chair: Phillip Eichorn,** Senior Director (Worldwide Safety and Regulatory)**, Pfizer**	11.20 **Chair: Rudi Scheerlinck,** Pharmacovigilance Risk Management Clinical Studies**, Galderma**	11.20 **Chair:**	11.20 **Chair: Magda Daudin,** Director, Pharmacovigilance QA Lead, **Idorsia**
11.25 **Harnessing AI to enhance signal detection capabilities** **Anupam Agarwal,** Vice President, Global Head of Drug Safety and PV**, Zogenix**			
11.45 **Quality. Cost. Speed. What really matters for PV automation adoption** **John Price,** Arriello Pharmacovigilance Advisory Board member**, Arriello**			
12.05 **The impact of AI on PV systems** **Mircea Ciuca,** Therapeutic Area Head Global Clinical Safety and Pharmacovigilance**, CSL Behring**	11.25 **Speaker presentation**	11.25 **Speaker presentation**	11.25 **The broad interfaces of PV with GXPs: Achieving the right standard** **Ranjana Khanna,** Director, Head Of PV, Quality Assurance**, Vifor pharma**

	11.45 **Silver sponsor presentation** **Reserved FILTRYX**	11.45 **Best practice in signal management across product life cycle** **Oleksandr Karpenko,** Principal Consultant**, Olexacon Limited**	11.45 **Silver sponsor presentation** **BIOCLINICA**
	12.05 **Latest developments in benefit-risk management** **Tjark Reblin,** Global Head Drug Safety and Risk Management**, Vifor Pharma**	12.05 **New age signal detection: Harnessing real world evidence integrated technologies** **Siva Kumar Buddha,** Global safety Physician Manager, Product safety and Risk Management**, Viatris**	12.05 **Developing COVID treatment in the midst of the pandemic: Protecting patients and pharmacovigilance compliance in extraordinary circumstances** **Eva van Engelen,** Associate Director, Global Patient Safety**, Gilead Sciences**
12.25 **Silver sponsor present)tion(Reserved for Mymeds and Me)**	12.25 **Lessons learned from the first phase implementation of a digital risk management platform** **Mariette Boerstoel Streefland,** SVP Patient Safety, Chief Safety Officer**, AstraZeneca**	12.25 **Silver sponsor presentation reserved for COVANCE**	12.25 **Silver sponsor presentation**
12.45 **Networking Lunch**			
13.55 **Roundtables** **Roundtable 1: How has Covid-19 impacted compliance and regulation in clinical trials and patient engagement?** **Sheila Khawaja,** Vice Chair**, WAPO** **+**			

Roundtable 2: Exploring medicines safety in maternal health
Belen Granell Villen, Quality and Safety Policy Executive**, The Association of the British Pharmaceutical Industry**
+
Roundtable 3: Exploring effective risk minimisation strategies: Insight from across industry
John Solomon, Head of Pharmacovigilance [UK & Ireland]**, Sanofi**
+
Roundtable 4: Achieving best practice in on-site and remote inspections
Laura Paola Boga, Head of Global Pharmacovigilance & EU Qualified Person for Pharmacovigilance**, Dompé farmaceutici S.p.A.**
+
Roundtable 5: Signal detection across small molecule generics and biosimilars
Howard Snow, Head Patient Safety Sandoz BioPharma & Generics, Novartis CMO & Patient Safety**, Novartis**
+
Roundtable 6: How does the UK PSMF comply with other territory PSMF requirements?
Monika Manske, Lead Quality Management and Deputy EEA QPPV, PSRM, Pharmacovigilance Safety & Risk Management**, Viatris**
+
Roundtable 7: How to manage different QPPV roles and responsibilities to meet local requirements?
Valentina Mancini, Director Pharmacovigilance, EU QPPV**, Shionogi Europe**
+
Roundtable 8: Understanding the regulatory guidance and stringencies in developing countries
Vipin Sethi, Global Pharmacovigilance Head**, Cadila Pharmaceuticals**
+
Roundtable 9: Meeting the requirements of case submission oversight from health authorities and business partners
Melanie Dullemond, PVQ Compliance Head, **Sanofi**
+
Roundtable 13: Practical applications & learnings of machine learning for PV scientists
Phillip Eichorn, Senior Director (Worldwide Safety and Regulatory)**, Pfizer**
+
Roundtable 15: The impact of Brexit within the regulatory process: Navigating the evolving landscape in the UK
Pav Rishiraj, UK QPPV, Head of Patient Safety – UK and Ireland, **Merck Serono and,** PV Expert Chair, **ABPI**
+

Roundtable 16: Streamlining of PV system compliance oversight metrics: Improving accuracy & oversight
Jan Cleerbout, Deputy EU QPPV Pharma, PV System Oversight**, Janssen**
+
Roundtable 17: The use of digital tools to achieve risk management objectives
Mark Perrott, Managing Partner, **Axian Consulting Ltd**
+
Roundtable 20: Adapting PV audit practices in a pandemic
Sharon Fabrizio, Head of Local PV Quality Oversight - Global Scope**, Sanofi**
+
Roundtable 21: Incorporating PV cyber skills within your organisation
Salvatore Cicirello, Senior Director, Safety Science and PASS**, Celgene, a BMS company**
+
Roundtable 22: Quality. Cost. Speed - Discussing the results from Arriello's brand new transatlantic PV automation adoption survey
John Price, Arriello Pharmacovigilance Advisory Board member**, Arriello and Kieran O'Donnell**

AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**QUALITY ASSURANCE AND COMPLIANCE**
14.50 **Chair: Omar Aimer,** Pharmacovigilance Specialist**, Brunel Canada/Sanofi**	14.50 **Chair: Amgad Shebl,** Director, Global Clinical Safety and Pharmacovigilance**, CSL Behring**	14.50 **Chair:**	14.50 **Chair: Mina Awad,** Pharmacovigilance Manager and QPPV, Middle East**, Kyowa Kirin International**
14:55 **AI applications and the role of VAERS in signal detection**	14:55 **Risk communication in Non-EU countries**	14:55 **Speaker presentation**	14:55 **Speaker presentation RESERVED NNIT**

<table>
<tr><td>Israel Gutierrez, VP, Pharmacovigilance and Drug Safety, Geron Corporation</td><td>Marjan Dzeparoski, RA and PV Manager, Bionika Pharmaceuticals</td><td>15.15 Silver sponsor presentation</td><td>15.15 Silver sponsor presentation(Reserved for Veeva)</td></tr>
<tr><td rowspan="2">15.15 Artificial Intelligence models to identify Adverse Events and Special Situations in the global and local scientific literature
Nicole Baker, CEO, biologit and Bruno Ohana, CTO, biologit</td><td rowspan="2">15.15 Silver sponsor presentation

RESERVED DELOITTE</td><td rowspan="3">15.35 Understanding the challenges from signal validation to the timely implementation of reference safety information
Katrien Soleme, Senior Director, Pharmacovigilance and Life Cycle Management Quality, Bristol Myers Squibb</td><td rowspan="2">15.35 Developing a global safety intelligence process
Heike von Treichel, Head of PV QMS and QPPV Office, Deputy European Qualified Person for Pharmacovigilance (Deputy EEA QPPV), Merck Healthcare</td></tr>
<tr><td rowspan="2">15.35 NLP-based AI for safety applications in Pharma
Jane Reed, Director, Life Sciences, Linguamatics</td></tr>
<tr><td>15.35 Safety considerations and risk management for biologics
Dragana Bundalo, Regulatory Affairs Associate, PharmaSwiss</td><td></td></tr>
<tr><td colspan="4">15.55 <u>Networking Break</u></td></tr>
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AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**VACCINE SAFETY**
16.25 **Chair:**	16.25 **Chair: Irene Morillo Alonso,** Clinical Assessor**, Spanish Agency of Medicines and Medical Devices**	16.25 **Chair: Colleen Moody,** Senior Manager, Safety Risk Management Scientist**, United Therapeutics**	16.25 **Chair: Dennis Vargo,** Vice President, Head of Drug Safety and Pharmacovigilance**, Akebia Therapeutics Inc.**
16.30 **Speaker presentation**	16.30 **Are we really managing risks or just administrating the risks?** **Uwe Gudat,** Head of Clinical Safety and Pharmacovigilance Clinical Safety and Pharmacovigilance**, Fresenius Kabi SwissBioSim**	16.30 **Our transformation journey: From compliance driven to proactive safety surveillance** **Markus Krupp,** Associate Director, Safety Signal Management & Data Analytics**, Merck Healthcare**	16.30 **Monitoring the safety of the COVID-19 Vaccines using open source technology** **Lionel Van Holle,** Safety Surveillance Lead**, UCB and** Founder, **OpenSourcePV**
16.50 **Considerations in deploying AI-enabled digital ICSR into production** **Vladimir Penkrat,** Associate Vice President - Global Head of Safety & Regulatory Affairs**, Indegene Inc**	16.50 **What is the impact of post-authorisation safety studies on benefit-risk balance for medicines?** **Liana Gross Martirosyan,** Alternate Member**, EMA - Pharmacovigilance Risk Assessment Committee**	16.50 **Silver sponsor presentation**	16.50 **Silver sponsor presentation**
17.10 **Speaker presentation**	17.10 **Cross-functional benefit risk strategy, management and documentation** **Elian Khazneh,** Head of Medical Safety Operations**, Merck Healthcare**	17.10 **Speaker presentation** RESERVED FOR EY	17.10 **Speaker presentation**

17.30 **Close of conference and drinks reception**

Day 2 – Thursday 7th October 2021

Morning Plenary

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

09.00 **Ibuprofen Safety: The Covid-19 Story**
Simon Sinclair, Chief Safety Officer**, Reckitt Benckiser**

09.20 **Platinum Sponsor presentation(reserved for ArisGlobal)**

09.40 **Key developments in Chinese PV Regulation and how to be a compliant affiliate**
Gloria Bustos, Head of PV EMEA & APAC / Global Patient Safety**, Baxter Healthcare**

10.00 **The strategic role of Affiliate Patient Safety in patient-centricity: Our journey**
Christina Bisschops-Kaltenbach, Global Head International Pharmacovigilance, Safety Risk Management**, Roche**

10.20 **Morning Break**

Track 1	Track 2	Track 3	Track 4

CASE PROCESSING	**TRANSLATIONAL SAFETY**	**PV OUTSOURCING**	**EMERGING MARKETS**
11.20 **Chair: Deanna Montes de Oca,** Global Head of PV Case Management**, Moderna**	11.20 **Chair: Nibedita Rath,** Scientific Director**, Open Source Pharma Foundation**	11.20 **Chair:**	11.20 **Chair:**
11.25 **How to perform effective safety reviews for case assessment** **Daniela Di Cosmo,** Senior Pharmacovigilance Manager, Global Pharmacovigilance**, Ferring**			
11.45 **Silver sponsor presentation** RESERVED FOR DELOITTE			
12.05 **Speaker Presentation**	11.25 **Patient-centric approach to translational safety** **Scott Chandler,** Global Head, Personalized Health Care (PHC) Safety, Product Development Safety**, Roche**	11.25 **Speaker presentation** RESERVED VEEVA	11.25 **The evolving role of PV in the Middle East and North Africa** **Tarik Messaoud,** Drug Safety Physician, **Independent**
	11.45 **PharmaPendium: Evolution journey of a search database to a knowledgebase**	11.45 **Silver sponsor presentation** **Reserved for Covance**	11.45 **Speaker presentation**

	for translational safety analytics **Catherine Noban**, Lead Product Manager – Content Assets, **Elsevier**		
	12.05 **Speaker presentation**	12.05 **Outsourcing and industry collaboration: What to outsource and what to keep in-house?** **Vipin Sethi,** Global Pharmacovigilance Head**, Cadila Pharmaceuticals**	12.05 **Exploring the regulatory landscape in Saudi Arabia, Oman, Egypt and UAE** **Syed Zaferuddin,** Global Pharmacovigilance Manager and QPPV**, Julphar**
12.25 **Silver sponsor presentation** **Reserved PHARSAFER**	12.25 **Silver sponsor presentation**	12.25 **Silver sponsor presentation Reserved for Product Life group)**	12.25 **Speaker presentation**
12.45 **Networking Lunch**			
13.55 **Roundtables** **Roundtable 3: Going beyond ICSR reporting: Recognising the critical relationship between patient safety and PV** **Loubna Alj,** Pharmacist & Epidemiologist**, Public Health Centre Anti Poison et de Pharmacovigilance du Maroc** **+** **Roundtable 4: State of case in-take automation: What are the solutions?** **Saeed Amin,** Vice President, Strategy**, Drogevate** **+** **Roundtable 5: Medication safety: New Era of best practice** **Fatima Ghethan,** Head of Quality and Medication Safety Unit**, King Abdullah Medical City (KAMC) and Alaa Yousef Ghidan,** Doctor**, The Higher Council for Science and Technology** **+** **Roundtable 6: Exploring the role of Real-World Data in pharmacovigilance** **Hadir Rostom,** President**, ISoP Egypt Chapter and** Lecturer**,** Faculty of Pharmacy**, Modern Sciences and Arts University**			

+

Roundtable 8: Ensuring patient safety and data privacy within de-centralised trials
Vivienne van de Walle, Medical Director**, Precare Trial and Recruitment Research Centre**

+

Roundtable 9: Exploring the critical paths of device safety in clinical investigations
Sylvie Bartus, Head of Clinical Safety, Surgical Structural Heart**, Edwards Lifesciences**

+

Roundtable 12: Moving to a globalised PV affiliate reporting model: Enhancing the value proposition
Rishi Chopra, Head of International Pharmacovigilance, Deputy EU QPPV & Deputy UK QPPV, **Biogen**

+

Roundtable 13: Exploring literature surveillance tools and processes
Paolo Voltolina, Director, Head of Regulatory Business Operations**, Lundbeck**

+

Roundtable 14: Switching from a de-centralised to centralised affiliate model in Europe: Considerations from mid-pharma
Attila Olah, Head Global Pharmacovigilance, Eu-Qppv**, Gedeon Richter and Albert Bekfi,** Head of Pharmacovigilance Operations**, Biomapas**

+

Roundtable 15: Early detection of safety signals in clinical trials
Sutirtha Mukhopadhyay, Senior Risk Management Physician**, Boehringer Ingelheim**

+

Roundtable 16: Highlighting the importance of ADRs in the Middle East and ensuring compliance at all levels
Muhammad Ashar Naeem, Global Director Pharmacovigilance and Medical Affair**, Jamjoom Pharma**

+

Roundtable 17: Exploring the challenges with R3 reporting standards in different countries and what are the potential solutions?
Andrea Maulwurf, Head of Corporate Pharmacovigilance, Global Leading Qppv**, Allergy Therapeutics**

CASE PROCESSING	**MEDICAL DEVICES**	**PATIENT ADVOCACY & CENTRICITY**	**SAFETY IN ONCOLOGY**

14.55 **Chair: Ellen Ravn Englev,** Senior Director, Case Management department, Safety Operations, Global Safety**, Novo Nordisk**	14.55 **Chair: Sylvie Bartus,** Head of Clinical Safety, Surgical Structural Heart**, Edwards Lifesciences**	14.55 **Chair: Ann Chivers,** Chief Executive**, Alström Syndrome UK**	14.55 **Chair: Céline Adessi,** Senior Director, Group Head, Oncology, Clinical Safety Science, **Roche**
15:00 **Examining the impact of Brexit on case processing** **Carmela Campana,** Deputy EU QPPV**, Istituto Biochimico Italiano G. Lorenzini**	15:00 **Opportunities of Digital Health for Patient Safety** **James Whitehead,** Patient Safety Medical Device Lead, **AstraZeneca**	15:00 **Fighting the fakes: Ensuring drug safety during a Pandemic** **Mary Lynne Van Poelgeest-Pomfret,** President**, World Federation for Incontinence and Pelvic Pain – WFIPP**	15:00 **Speaker presentation**
		15.20 **How can pharma improve healthcare for the patient: What does patient centricity really mean?** **Kristof Vanfraechem**, Founder and CEO, **Data For Patients**	15.20 **Optimising early clinical investigations in cancer immunotherapy by increasing the translational value of non-clinical activities** **Estelle Marrer-Berger,** Toxicology Project Leader**, Roche**
		15.40 **Speaker presentation**	15.40 **Biosimilar safety in the world of oncology** **Andrea Oliva**, Head of Pharmacovigilance, Italy Product Safety & Risk Management, **Viatris**
15.20 **Speaker presentation**	15.20 **Silver sponsor presentation**		

15.40 **Experiences using machine translation to support global case in-take** **Adrian Maynier,** Head of Safety Systems**, UCB**	15.40 **Adverse events and device deficiencies from medical device studies: Sponsor safety assessments and independent adjudication** **Talia Milosevic,** Manager, Clinical Safety, Surgical Structural Heart**, Edwards Lifesciences**		
16.00 **Silver sponsor presentation**	16.00 **Silver sponsor presentation**	16.00 **What would personalised safety, delivered in a patient centric way, look like from a patient's perspective** **Jacquelien Noordhoek**, President**, CF Europe**	16.00 **Silver sponsor presentation**

16.20 **Close of conference**