WORLD

DRUGSAFETY

CONGRESS EUROPE

THE VIRTUAL EDITION

14-16th October 2020

WORLD DRUGSAFETY CONGRESS EUROPE

World Drug Safety Congress Europe is going virtual!

Due to COVID-19, this year's event arrives at an unprecedented time. Therefore, we will be moving this year's congress online. Instead of you coming to us we will be coming to you, virtually!

Terrapinn will be providing a virtual venue for the pharmacovigilance community to gather. We will continue to connect the life science sector to empower patients, regulators, physicians, pharma, biotech and consumers to make the best drug safety decisions. We are using the current landscape to our advantage to bring exciting things that are now possible due to the virtual aspect.

Whilst we cannot meet again this year -and we will miss seeing your faces- we are committed to delivering our usual high standards by using the most exciting digital tools in the most innovative way.

Join us from the comfort of your home!

WORLD DRUGSAFETY CONGRESS EUROPE

WORLD DRUGSAFETY CONGRESS EUROPE

2020 Speakers

(Please note: "*" denotes a speaker that has confirmed their participation in the Congress, but currently discussing their topic and place in the agenda with us)

1. **Patrick Caubel, SVP,** Head of Pharmacovigilance, **Pfizer**
2. **Felix Arellano**, Global Head Safety Risk Management, **Roche**
3. **Howard Snow,** Head Patient Safety, **Sandoz Biopharmaceuticals**, Chief Medical Office and Patient Safety, **Novartis**
4. **Phil Tregunno,** Group Manager, Vigilance, Intelligence and Research, **MHRA**
5. **Ale Maria Vasquez-Gragg,** VP, Global Head of Pharmacovigilance, **Orchard Therapeutics**
6. **David Chonzi,** VP, Head of Pharmacovigilance and Epidemiology (PVE)**, Allogene Therapeutics**
7. **Scott Chandler,** Global Head, Personalised Health Care (PHC) Safety, Product Development Safety, **Roche**
8. **Salvatore Giorgio Cicirello**, Senior Director Pharmacovigilance Innovation, Global Drug Safety & Risk Management, **Celgene**
9. **Gloria Bustos,** Head of Pharmacovigilance EMEA and APAC, **Baxter Healthcare Corporation**
10. **Uwe Gudat,** Head of Clinical Safety & Pharmacovigilance Clinical Safety & Pharmacovigilance, **Fresenius Kabi**
11. **Andrea Maulwurf,** EU-QPPV, Head of Pharmacovigilance, **Allergy Therapeutics**
12. **Lisa Benaise,** Global Risk Minimization Physician, Device Safety/ Risk Management/ Pharmacovigilance, **Nestle Skin Health**
13. ***Sally Lee**, Senior Director, Epidemiology, Global Drug Safety and Risk Management, **Celgene**
14. **Rie Matsui,** Director, Regional Labeling Head of Asia**, Pfizer**
15. **Sutirtha Mukhopadhyay,** Global Safety Officer, **Sanofi**
16. **Marjan Dzeparoski,** RA&PhV Manager**, Bionika Pharmaceuticals**
17. **Elizabeth Baker,** Pharmaceutical Policy Program Director, **Physicians Committee for Responsible Medicine**
18. **Priya Singhal,** Global Head of Safety and Regulatory Sciences, Biogen
19. ***Richard Wolf,** Head of PV Operations**, CSL-Behring**
20. **Jackie Roberts,** VP Scientific Affairs, Governance**, Accord Healthcare**
21. **Omar Aimer,** Pharmacovigilance Specialist**, Independent (Ne Sanofi Canada)**
22. **Bert Van Leeuwen,** Deputy QPPV**, Astellas**
23. **Mate Balazs,** Country Head – Patient Safety – Hungary, National QPPV – Hungary, **Novartis**
24. **Tarik Messaoud,** Drug Safety Specialist Pharmacovigilance Specialist, **Independent**
25. **Margherita D'Antuono,** EU QPPV**, Italfarmaco**
26. **Monika Manske,** Lead Quality Management, PSRM, Pharmacovigilance Safety & Risk Management**, Mylan Healthcare GmbH**
27. **Julia Appelskog,** Head of PV Strategy Office, Global Patient Safety, **Merck KGaA**

28. **Raphael Pareschi,** Pharmacovigilance Associate Director**, Merck Sharp & Dohme**
29. **Giovanni Furlan,** Safety Risk Lead, Director, **Pfizer**
30. **James Whitehead,** Patient Safety Medical Device Lead, **AstraZeneca**
31. **Marcus Schartau,** Safety Surveillance Risk Management Specialist, Safety Surveillance, **Novo Nordisk**
32. **Peter De Veene,** QPPV (France), **Alexion Pharmaceuticals, Inc**
33. **Liana Gross-Martirosyan,** Alternate PRAC Member**, Medicines Evaluation Board Netherlands**
34. **Marco Sardella**, Chief Pharmacovigilance Officer, European QPPV, **ADIENNE Pharma**
35. **Maritess Esguerra,** Principal Pharmacovigilance Process Leader**, Genentech**
36. **John Solomon**, Head of Pharmacovigilance-UK & Ireland, **Sanofi**
37. **Jaylaxmi Nalawade,** Associate Director, Pharmacovigilance and REMS, **LUPIN SOMERSET**
38. **Lucy Hampshire,** Senior Director, Medicines Quality Organisation – International, **Eli Lilly and Company Limited**
39. **Marina Suvakov,** Director**, Otsuka Europe Development and Commercialisation Ltd**
40. **Valentina Mancini,** Director Pharmacovigilance, EU QPPV, **Shionogi**
41. **Mary Lynne Van Poelgeest-Pomfret,** President**, World Federation for Incontinence and Pelvic Pain (WFIP)**
42. **Lionel Van Holle,** Safety Surveillance Lead, **UCB** and Founder, **OpenSourcePV**
43. **Matthias Bödding**, Senior Director, **Merck KGaA**
44. **Laura Paola Boga**, Global Head of Pharmacovigilance & EU QPPV, **Dompé farmaceutici s.p.a.**
45. **Raj Bhogal,** Head of Audits and Inspections, R&D Quality, **Jazz Pharmaceuticals**
46. **Nibedita Rath,** Scientific Director**, Open Source Pharma Foundation**
47. **Eva Van Engelen,** Associate Director Pharmacovigilance & Epidemiology Benelux, **Gilead Sciences**
48. **Ranjana Khanna**, Director, Head PV Quality Assurance, **Vifor Pharma**
49. **Jorge Gonzalez Borroto,** Senior Toxicologist & Nonclinical Safety Adviser, **Ferrer Internacional S.A**
50. ***Haris Shaikh,** Former Senior Director Pharmacovigilance, **Orchard Therapeutics**
51. **Fabian Heisig,** Head of Global Drug Safety and QPPV, **Grunenthal**
52. **Yvonne Nanciu,** Senior Manager Pharmacovigilance & Medical Information, Affiliate Safety Representative (ASR), QPPV (Switzerland), **Abbvie**
53. **Sylvie Bartus,** Director Clinical Affairs, Head of Global Safety, Surgical Structural Heart, **Edwards Lifescience**
54. **Tatjana Ajhler Duretek,** Head of Medical Affairs and Pharmacovigilance with role of EU QPPV, **Belupo Pharmaceuticals & Cosmetics Inc**
55. **Gabrielle Amselem,** Deputy EUQPPV - PSMF Manager, **Alexion**
56. ***Chetan Shatapathy**, Principal Pharmacovigilance Physician, **AstraZeneca**
57. **Rudi Scheerlinck**, Global Head Pharmacovigilance Risk Management, **Galderma**
58. ***Philip Eichorn,** Senior Director Worldwide Safety & Regulatory**, Pfizer Pharmaceuticals**
59. **Rodrigo Ruiz Ramirez,** Head of Country Pharmacovigilance Mexico**, Bristol-Myers Squibb**
60. **Leona Houghton,** Senior Director, PV Quality & Compliance, **Jazz Pharmaceuticals**

61. **Andrea Oliva,** Head of Pharmacovigilance, **Italy, Mylan**
62. **Daniela Di Cosmo,** Pharmacovigilance Manager, **Ferring Pharmaceuticals A/S**
63. **Muhammed Ashar Naeem,** Director Pharmacovigilance and Medical Affairs, **JamJoom Pharma**
64. **Anupam Agarwal,** Vice President Global Head Of Drug Safety And Pv, **Zogenix**
65. **Paola Kruger,** Expert Patient, **EUPATI**
66. **Kristof Huysentruyt,** Director and Head of Global Safety Solutions, **UCB**
67. **Nadia Español,** Global Medical Safety Manager, **Galapagos**
68. **Jens-Ulrich Steggman, S**VP, Head Clinical Safety and Pharmacovigilance, **GSK Biologicals** and EU QPPV, **GSK and ViiV Healthcare**
69. **Andrew Erdman**, Vice President, Global Head of Early Development Safety, **Genentech**
    Vincenzo Cannizzaro, Regulatory Solutions, **GE Healthcare**
70. **Frederick Sannajust,** Former Executive Director, Head of Safety & Exploratory Pharmacology**, Merck Research Laboratories, MERCK & Co., Inc. (MSD)**
71. **Jean-Pierre Valentin**, Global Head of Toxicology, **UCB-Pharma**
72. **Antonia Coppin-Renz,** Director, TA Lead Digital Therapeutics & Deputy EU QPPV, **Otsuka Pharmaceutical Development & Commercialisation Europe**
73. **Belen Granell Villen,** Quality & Safety Policy Executive, **ABPI**
74. **Mircea Ciuca,** Global Therapeutic Area Head, Global Clinical Safety and Pharmacovigilance**, CSL Behring**
75. **Avinash Kakade,** SGM, Global Head- Pharmacovigilance, **Lupin**
76. **Shaun Mohan,** Senior Medical Safety Scientist, Product Development Safety, **Genentech**
77. **Richard Brennan,** Preclinical Safety, **Sanofi** & **DruSafe Secondary Pharmacology Working Group**
78. **Kate Gofman,** Global Safety Physician, AI & Blockchain Innovator, **AstraZeneca**
79. **Heike Von Treichel,** Head of QPPV Office and Deputy EEA QPPV, **Merck Gruppe**
80. **Philippa Evans,** Senior Safety Medical Writer, **Novo Norodisk**
81. **Heyde Patricia Zuluaga Arias**, Vice President and Academic Committee Coordinator, **Colombia Pharmacovigilance Association**
82. **Wally Landsberg,** Director, Therapeutic Area Lead CNS**, Otsuka Pharmaceutical Development & Commercialisation Europe**
83. **Magda Daudin,** Quality Assurance - Pharmacovigilance Domain Expert - Team lead - Associate Director, **Janssen**
84. **Jolanda de Bruijne,** Sr. Dir. Quality Management Systems, **Astellas**
85. ***Sheila Khawaja,** Vice Chair, **WAPO Association**
86. **Ariane Stollenwerk**, Germany, Austria and Switzerland Safety Leader, **UCB**
87. **Lykke Graff**, Head of Global Safety, **Leo Pharma**
88. **Jean-Christophe Delemeau**, Head Of Pharmacovigilance Policy Strategy, **Bayer**

89. **Maria Maddalena Lino**, Safety Risk Lead, Director, **Pfizer**
90. **Mohamed Abdel Hady**, Pharmacovigilance and Epidemiology Manager, **Gilead Sciences**
91. **Santiago Garnica, Drug Safety Co-ordinator, Vitalis**
92. **Mike Cohen,** President, Institute for Safe Medication Practices
93. **Lubna Merchant,** Associate Director of of Division of Medication Error Prevention and Analysis of OSE of CDER, **FDA**
94. **Max Waschbusch,** TA Head Cardiovascular and Metabolism, **CSL- Behring**
95. **Annie Moisan,** Translational Bioengineering Program Director, **Wellcome Leap**
96. **Peter-Christoph Schulz,** VP Global Pharmacovigilance and EU QPPV, **Ipsen**
97. **Aman Wasan,** Senior Vice President, Business Development & Client Partners, RoW, **Aris Global**
98. **Emmanuel Belabe,** Associate Vice President, Safety Product Management**, Aris Global**
99. **Dave Nestor,** Director**, Deloitte**
100. **Michael Braun-Boghos**, Senior Director Safety Strategy, **Oracle Health Sciences**
101. **Kim Brown,** Department Manager C5Research CEC, Cleveland Clinic
102. **Irene Morillo Alonso,** Clinical Assessor, **Spanish Agency for Medicines and Medical Devices (AEMPS)**
103. **Andleeb Arshad**, RA Manager for UK and Nordics, **Edwards Life Science**
104. **Tarak Thakker**, Director – Professional Services, **RxLogix**

WORLD DRUGSAFETY CONGRESS EUROPE

Agenda at a glance

Day 1- Wednesday 14th October 2020

- AI + Automation
- Risk Management
- Quality Assurance and Compliance
- Case Processing
- Translational Safety

Day 2- Thursday 15th October 2020

- Signal Detection
- Patient Advocacy
- RWE+ Big Data
- Cell and Gene Therapy
- PV Outsourcing

Day 3- Friday 16th October 2020

- Regulation
- Medical Devices
- Spotlight Session
- Developing Markets

Day 1- Wednesday 14th October 2020

NB. All times are to Amsterdam, CET

Morning Plenary

9.55	**Terrapinn's Opening Remarks**
10.00	**Pharmacovigilance in times of a pandemic** **Jens-Ulrich Steggman,** SVP, Head Clinical Safety and Pharmacovigilance, **GSK Biologicals** and EU QPPV, **GSK and ViiV Healthcare**
10.20	**Evolve or Revolutionize: opportunities to transform the future of pharmacovigilance** **Michael Braun-Boghos**, Senior Director Safety Strategy, **Oracle Health Sciences**
10.40	**Pharmacovigilance: Back to the future – returning to our roots** Sub-themes: Is pharmacovigilance primarily a data management discipline? Is more of the same more, or less? Who are our real customers and what do they really need? Towards knowledgeable action and actionable knowledge **Uwe Gudat,** Head of Clinical Safety & Pharmacovigilance Clinical Safety & Pharmacovigilance, **Fresenius Kabi**
11.00	**Q+A Live Panel**

	AI + AUTOMATION	RISK MANAGEMENT	CASE PROCESSING
	Moderator **Kate Gofman,** Global Safety Physician, AI & Blockchain Innovator, **AstraZeneca**	*Moderator* **Marcus Schartau,** Safety Surveillance Risk Management Specialist, Safety Surveillance, **Novo Nordisk**	*Moderator* **Heike Von Treichel,** Head of QPPV Office and Deputy EEA QPPV, **Merck Gruppe**
11.15	**Application and Validation of Intelligent Automation Technology in PV: Exploring Opportunities within the Individual ICSR Process** **Kristof Huysentruyt,** Director and Head of Global Safety Solutions, **UCB**	**Assessing the effectiveness of risk minimisation** **Liana Gross-Martirosyan,** Alternate PRAC Member, **Medicines Evaluation Board Netherlands**	

11.35	**AI + Automation in Case processing.** **Tarak Thakker**, Director – Professional Services, **RxLogix**	**Drug and device AE reporting** **Lisa Benaise,** Global Risk Minimization Physician, Device Safety/ Risk Management/ Pharmacovigilance, **Nestle Skin Health**	
11.55	**Technology and big data driving Automation from audit risk-based planning to audit reporting** **Magda Daudin,** Quality Assurance - Pharmacovigilance Domain Expert - Team lead - Associate Director, **Janssen**	**Paradoxical effects of communicating drug information on adverse drug reactions** **Giovanni Furlan,** Safety Risk Lead, Director, **Pfizer**	**Market Research Programs and Patient Support Programs: challenges and expectations** **Daniela Di Cosmo,** Pharmacovigilance Manager, **Ferring Pharmaceuticals A/S**
12.15	**Augmented Intelligence and the evolving role of the PharmacoVigilance professional:** **A deep dive into the PV cyber skills required to leverage new technologies potential and How can Drug Safety Organizational enable a digital transformation that benefits both patients and PV professionals** **Salvatore Giorgio Cicirello**, Senior Director Pharmacovigilance Innovation, Global Drug Safety & Risk Management, **Celgene**	**Risk management beyond routine pharmacovigilance** **Jaylaxmi Nalawade,** Associate Director, Pharmacovigilance and REMS, **LUPIN SOMERSET**	**Digital Media and e-commerce initiatives: challenges for PV** **Valentina Mancini,** Director Pharmacovigilance, EU QPPV**, Shionogi**
12.35	**Q+A Live Panel**	**Q+A Live Panel**	**Q+A Live Panel**

Afternoon Plenary

12.55	**Chair's Remarks**

	Patrick Caubel, SVP, Head of Pharmacovigilance, **Pfizer**
13.00	**Keynote Panel** **PV Departments: From a cost and compliance centre to a scientific and value adding function** **Moderator: Patrick Caubel, SVP,** Head of Pharmacovigilance, **Pfizer** **Lykke Graff**, Head of Global Safety, **Leo Pharma** **Peter-Christoph Schulz,** VP Global Pharmacovigilance and EU QPPV, **Ipsen**
13.40	**Moving from a Fragmented to a Unified Pharmacovigilance Solution** **Jennfer Markey**, VP Vault Safety Strategy and Consulting, EU, **Veeva**

	AI + AUTOMATION	QUALITY ASSURANCE AND COMPLIANCE	TRANSLATIONAL SAFETY
	Moderator **Omar Aimer,** Pharmacovigilance Specialist**, Independent (Ne Sanofi Canada)**	*Moderator* **TBC**	*Moderator* **Matthias Bödding**, Senior Director, **Merck KGaA**
14.00	**Open source technology in supporting safety** **Lionel Van Holle,** Safety Surveillance Lead, **UCB** and Founder, **OpenSourcePV**	**Training in PV: what is the difference between necessity, comfort and luxury** **Ranjana Khanna**, Director, Head PV Quality Assurance, **Vifor Pharma**	**Drug-induced QTc prolongation and torsades de pointes: evolving ICH-E14 and S7B guidelines in light of emerging data** **Jean-Pierre Valentin**, Global Head of Toxicology, **UCB-Pharma**
14.20	**Incorporating Automation in PV – A Practical Approach** **Emmanuel Belabe,** Associate Vice President, Safety Product Management**, Aris Global**	**Building in quality to ensure "getting it right first time"** **Leona Houghton,** Senior Director, PV Quality & Compliance, **Jazz Pharmaceuticals**	**Drugs can fail because of effects on arterial blood pressure - how can we improve the preclinical predictivity of drug-induced hemodynamic changes?** ***Review of state-of-the-art strategies for better translation to clinic*** **Frederick Sannajust,** Independent, Former Executive Director, Head of Safety & Exploratory Pharmacology**, Merck Research Laboratories, MERCK & Co., Inc. (MSD)**

14.40	**WEB-RADR Update** **Phil Tregunno,** Group Manager, Vigilance, Intelligence and Research, **MHRA**	**The local QPPV's Value in a Global PV System** **Eva Van Engelen,** Associate Director Pharmacovigilance & Epidemiology Benelux, **Gilead Sciences**	**Secondary Pharmacology Screening in Pharmaceutical R&D: A survey of practices and experiences across 18 companies** **Richard Brennan,** Preclinical Safety, **Sanofi** & **DruSafe Secondary Pharmacology Working Group**
15.00	**Q+A Live Panel**	**Q+A Live Panel**	**Q+A Live Panel**

	AI + AUTOMATION	QUALITY ASSURANCE AND COMPLIANCE	TRANSLATIONAL SAFETY
	Moderator **Omar Aimer,** Pharmacovigilance Specialist**, Independent (Ne Sanofi Canada)**	*Moderator* *TBC*	*Moderator* **Scott Chandler,** Vice President and Global Head, Licensing and Early Development (LEAD) Safety**, Roche**
15.20	**Where does Drug Safety fit in the Biopharma operating model of the future?** **Dave Nestor,** Director**, Deloitte**	**PV agreements: Managing business relationships** **Marina Suvakov,** Director**, Otsuka Europe Development and Commercialisation Ltd**	**Panel: Translational Methodologies and Predictive Safety** **Led by Scott Chandler,** Global Head, Personalised Health Care (PHC) Safety, Product Development Safety, **Roche** **Andrew Erdman**, Vice President, Global Head of Early Development Safety, **Genentech** **Annie Moisan,** Translational Bioengineering Program Director, **Wellcome Leap**
15.40	**Adopting new technology: mitigating the natural apprehensiveness to changing methodologies for an improvement in success rates** **Omar Aimer,** Pharmacovigilance Specialist**, Independent (Ne Sanofi Canada)**	**Compliant approaches to the safety aspect of the sponsor Trial Master File** **Lucy Hampshire,** Senior Director, Medicines Quality Organisation – International, **Eli Lilly and Company Limited**	
16.00	**Medical literature monitoring for drug safety- a stepwise approach for automating a tedious, labour intensive process** **Mark Drinkwater,** Market Development Director, **Dialog Solutions** **Angela Duma**, Product Manager Lead, **Dialog Solutions**		**Highlighting policy work to support the use of human biology-based preclinical methods** **Elizabeth Baker,** Pharmaceutical Policy Program Director, **Physicians Committee for Responsible Medicine**
16.20	**Q+A Live Panel**	**Q+A Live Panel**	**Q+A Live Panel**

16.40	Roundtables • Maintenance of a worldwide PSMF Monika Manske, Lead Quality Management, PSRM, Pharmacovigilance Safety & Risk Management, Mylan Healthcare GmbH + Margherita D'Antuono, EU QPPV, Italfarmaco + Gabrielle Amselem , Deputy EUQPPV - PSMF Manager, Alexion • Safety Data Exchange Agreements Nadia Español, Global Medical Safety Manager, Galapagos • **Preparing for Inspections** **Raj Bhogal,** Head of Audits and Inspections, R&D Quality, **Jazz Pharmaceuticals** **+** **Laura Paola Boga**, Global Head of Pharmacovigilance & EU QPPV, **Dompé farmaceutici s.p.a.** • **The Effect of Brexit on Pharmacovigilance and Safety Reporting** **Jennifer Markey,** VP Vault Safety Strategy and Consulting, **Veeva** • **AI for case intake and processing – what progress has been made, lessons learnt, and open issues** *Rave Harpaz, Senior Director Research and Data Science,* Oracle Health Sciences **Michael Braun-Boghos**, Senior Director Safety Strategy, **Oracle Health Sciences** • **Automation in Signal Management & Predictive Signal Detection.** **Awais Khan**, Product Director & SME, **RxLogix**
End of Day 1	

Day 2- Thursday 15th October 2020

Morning Plenary

	Chair's Opening Remarks **Felix Arellano**, Global Head Safety Risk Management, **Roche**
10.00	**Keynote Panel: How would PV look in 2030?** **Felix Arellano**, Global Head Safety Risk Management, **Roche** **David Chonzi, VP,** Head of Pharmacovigilance and Epidemiology (PVE), **Allogene Therapeutics** **Ale Maria Vasquez-Gragg,** VP, Global Head of Pharmacovigilance, **Orchard Therapeutics** **Michael Braun-Boghos**, Senior Director Safety Strategy, **Oracle Health Sciences**

	SIGNAL DETECTION & MANAGEMENT	RISK MANAGEMENT	RWE & BIG DATA
	Moderator **Priya Singhal,** Global Head of Safety and Regulatory Sciences, Biogen	*Moderator* **Ariane Stollenwerk**, Germany, Austria and Switzerland Safety Leader, **UCB**	*Moderator* *TBC*
11.15		**Local implementation of additional Risk Minimization Measures** **Ariane Stollenwerk**, Germany, Austria and Switzerland Safety Leader, **UCB**	**Use cases in drug safety and what lessons we can learn from those** **Anupam Agarwal**, Vice President Global Head Of Drug Safety And PV, **Zogenix**
11.35		Title TBC Hadir Rostom	Reserved IQVIA Jane Reed, Director of Life Sciences at Linguamatics an IQVIA company
11.55	**The Eudravigilance Signal Detection Pilot, the implementation and its results in one company and the second prolongation of the pilot, sense or nonsense**	***The Covid-19 pandemic impact on PV activities*** ***Avinash Kakade,*** *SGM, Global Head-Pharmacovigilance,* ***Lupin***	Initiatives to Improve Patient Safety: Guidance, and Patient Involvement **Belen Granell Villen,** Quality & Safety Policy Executive, **ABPI**

	Bert Van Leeuwen, Deputy QPPV**, Astellas**		
12.15	**Signal detection in clinical development - from reactive to proactive and predictive safety** **Mircea Ciuca,** Global Therapeutic Area Head, Global Clinical Safety and Pharmacovigilance**, CSL Behring**	***Spotlight Session*** **Regulations and Standards in Asia: Challenges and new trends** **Gloria Bustos,** Head of Pharmacovigilance EMEA and APAC, **Baxter Healthcare Corporation**	**Social media from a Pharmacovigilance perspective** **Andrea Oliva,** Head of Pharmacovigilance, Italy, **Mylan**
12.35	**Q+A Live Panel**	**Q+A Live Panel**	**Q+A Live Panel**
12.55	Roundtables • **Signal detection in small to medium-sized companies** **Rudi Scheerlinck,** Global Head Pharmacovigilance Risk Management, **Galderma** **+ Maria Maddalena Lino**, Safety Risk Lead, Director, **PRfizer** • **Signal Detection for Orphan Drugs (quantitative vs qualitative approaches)** **Marco Sardella**, Chief Pharmacovigilance Officer, European QPPV, **ADIENNE Pharma** • **COVID-19 Vaccine Safety Reporting and Assessment: Challenges and Strategies** **Thomas Leigh**, Executive Medical Director & Head of PSS Medical Patient Safety Solutions & Adjudication (PSS&A), **Covance** • **Application of blockchain in the pharmaceutical industry + pharmacovigilance** **Kate Gofman,** Global Safety Physician, AI & Blockchain Innovator, **AstraZeneca** • Techniques and Technologies for Global PVRM Teams: task management for compliance and productivity **Kevin Fetterman**, Sr. Director Business Development, **Feith** • GVP-like legislation outside EU: are you compliant? **Martijn van de Leur** (moderator) – Head of Global Pharmacovigilance, **Biomapas** **Lidia Maksyutkina** (expert) – EAEU QPPV / Regional PV Manager CIS, **Biomapas**		

Afternoon Plenary

13.45	**Chair's Remarks** **Mike Cohen,** President, I**nstitute for Safe Medication Practices**
13.50	**Enabling Expedited Adoption of Technology in Pharmacovigilance** **Aman Wasan,** Senior Vice President, **Aris Global**
14.10	**Keynote Panel: Medication Error Prevention** **Mike Cohen,** President, I**nstitute for Safe Medication Practices** **Lubna Merchant,** Associate Director of of Division of Medication Error Prevention and Analysis of OSE of CDER, **FDA** **Santiago Garnica, Drug Safety Co-ordinator, Vitalis**

	SIGNAL DETECTION & MANAGEMENT	RISK MANAGEMENT	PV OUTSOURCING + PATIENT ADVOCACY
	Moderator **Max Waschbusch,** TA Head Cardiovascular and Metabolism, **CSL-Behring**	*Moderator* *TBC*	*Moderator* **Heyde Patricia Zuluaga Arias**, Vice President and Academic Committee Coordinator, **Colombia Pharmacovigilance Association**
15.00	**Assessing causality or assessing strength of association – ICSR vs Signal detection!** **Sutirtha Mukhopadhyay,** Global Safety Officer, **Sanofi**	**Pharmacovigilance Risk Management Plan. Risk Minimization Action Plan (RiskMAP) for a new approval medicine.** **Jorge Gonzalez Borroto,** Senior Toxicologist & Nonclinical Safety Adviser, **Ferrer Internacional S.A**	**Title TBC** **Mate Balazs,** Country Head – Patient Safety – Hungary, National QPPV – Hungary, **Novartis**

15.20	**Key lessons learnt from Grünenthal's newly implemented signalling process** **Fabian Heisig,** Head of Global Drug Safety and QPPV, **Grunenthal**	**Title TBC** **Peter De Veene,** QPPV (France), **Alexion Pharmaceuticals, Inc**	
15.40		**Title TBC** **Haris Shaikh,** Former Senior Director, Pharmacovigilance, **Orchard Therapeutics**	**Pharmacovigilance and patient safety: Trends of a new decade** **Heyde Patricia Zuluaga Arias**, Vice President and Academic Committee Coordinator, **Colombia Pharmacovigilance Association**

16:00	**Q+A Live Panel**	**Q+A Live Panel**	**Q+A Live Panel**
16:20	• **Patient Centricity** **Mary Lynne Van Poelgeest-Pomfret,** President**, World Federation for Incontinence and Pelvic Pain (WFIP)** • **Digital therapeutics: How Older Adults can benefit from Technical Innovations** **Led by Antonia Coppin-Renz**, Director, TA Lead Digital Therapeutics & Deputy EU QPPV, **Otsuka Pharmaceutical Development & Commercialisation Europe** **+** **Participated by Wally Landsberg,** Director, Therapeutic Area Lead CNS**, Otsuka Pharmaceutical Development & Commercialisation Europe** • **How safety physicians feel about automation: positives, future and threats** **Howard Snow,** Head Patient Safety, **Sandoz Biopharmaceuticals**, Chief Medical Office and Patient Safety, **Novartis** • **How are companies utilising development RMP's?** **Philippa Evans,** Senior Safety Medical Writer, **Novo Norodisk** • **Developing a map for clinical device safety and how to cover all aspects (workshop exercise)** **Sylvie Bartus**, Director Clinical Affairs, Head of Global Safety, Surgical Structural Heart, **Edwards Lifescience** • Leveraging new technologies for better signal detection and management – the role of AI, big data, and predictive analytics ***Rave Harpaz,*** *Senior Director Research and Data Science,* Oracle Health Sciences **Michael Braun-Boghos**, Senior Director Safety Strategy, **Oracle Health Sciences**		

	• **How Digital Transformation will Change Outsourcing Trends within Pharmacovigilance** **Aman Wasan,** Senior Vice President, **Aris Global**

	End of Day 2

Day 3- Friday 16th October 2020

Morning Session

11.55	**Roundtables:** • **Drug Safety In Biosimilars and Biologics** **Yvonne Nanciu,** Senior Manager Pharmacovigilance & Medical Information, QPPV (Switzerland), **Abbvie** • **PV Requirements in Brazil / ICH implementation** **Raphael Pareschi,** Pharmacovigilance Associate Director**, Merck Sharp & Dohme** • **Local Implementation of Risk minimisation activities** **John Solomon**, Head of Pharmacovigilance-UK & Ireland, **Sanofi** • **Labelling in Non-EU Countries** **Marjan Dzeparoski,** RA&PhV Manager**, Bionika Pharmaceuticals** • How to expand a safety department Andrea Maulwurf, Head of Pharmacovigilance, Allergy Therapeutics

Afternoon Plenary

12.45	**Chair's remarks** **Sylvie Bartus,** Director Clinical Affairs, Head of Global Safety, Surgical Structural Heart, **Edwards Lifescience**
12.50	**Keynote Panel:** LAs **Sylvie Bartus,** Director Clinical Affairs, Head of Global Safety, Surgical Structural Heart, **Edwards Lifescience**

	Lisa Benaise, Global Risk Minimization Physician, Device Safety/ Risk Management/ Pharmacovigilance, **Nestle Skin Health** **Kim Brown,** Department Manager C5Research CEC, **Cleveland Clinic** **Andleeb Arshad**, RA Manager for UK and Nordics, **Edwards Life Science** **Irene Morillo Alonso,** Clinical Assessor, **Spanish Agency for Medicines and Medical Devices (AEMPS)**

	SPOTLIGHT SESSIONS	REGULATION	MEDICAL DEVICES+DEVELOPING MARKETS
	Moderator **Mohamed Abdel Hady**, Pharmacovigilance and Epidemiology Manager, **Gilead Sciences**	*Moderator* *TBC*	**Marjan Dzeparoski,** RA&PhV Manager**, Bionika Pharmaceuticals**
13:55	**Need of Open Source Pharmacovigilance** **Nibedita Rath,** Scientific Director**, Open Source Pharma Foundation**	**Processing of direct healthcare professional communications (DHPCs) – same letter in different regions, EU and non EU.** **Tatjana Ajhler Duretek,** Head of Medical Affairs and Pharmacovigilance with role of EU QPPV, **Belupo Pharmaceuticals & Cosmetics Inc**	
14:15	**Outlook of e-labelling** **Rie Matsui,** Director, Regional Labeling Head of Asia**, Pfizer**	**Managing pharmacovigilance compliance in an uncertain regulatory world, the issues of managing change** **Jackie Roberts,** VP Scientific Affairs, Governance**, Accord Healthcare**	**Achieving holistic Patient Safety – How AZ approached incorporating Device Requirements into our Pharmacovigilance System** **James Whitehead**, Patient Safety Medical Device Lead, **AstraZeneca**
14:35		**How to create an effective PV strategy?**	**Challenges of implementing PV process in Mena Region**

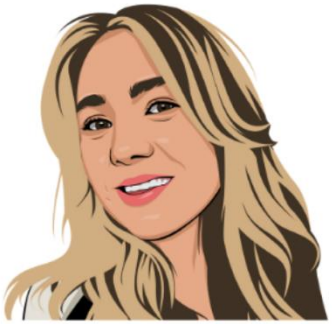
		Julia Appelskog, Head of PV Strategy Office, Global Patient Safety, **Merck KGaA**	**Muhammed Ashar Naeem,** Director Pharmacovigilance and Medical Affairs, **JamJoom Pharma**
14:55	**Q+A Live Panel**	**Q+A Live Panel**	**Q+A Live Panel**

	Keynote Panel
15:15	**Panel: New opportunities for improving the E-Submission Landscape** **Jean-Christophe Delemeau**, Head Of Pharmacovigilance Policy Strategy, **Bayer**

15:55	**Roundtables:** • **Drug-Device Combination Products: How the evolving global regulatory landscape will impact PV operations** **Tarik Messaoud,** Drug Safety Specialist Pharmacovigilance Specialist, **Independent** • **New challenges for PV in Mexico** **Rodrigo Ruiz Ramirez,** Head of Country Pharmacovigilance Mexico**, Bristol-Myers Squibb** • **Impact of FDA PMSR and EU MDR regulations on reference safety information table for combination products** **Maritess Esguerra,** Principal Pharmacovigilance Process Leader**, Genentech** • Challenges of Global PV function in a changing business environment – how to ensure efficient collaboration between global and local teams? Jolanda de Bruijne, Sr. Dir. Quality Management Systems, Astellas
	End of Conference

WORLD DRUGSAFETY CONGRESS EUROPE

Contact Us



ANASTASIA BERETSOS

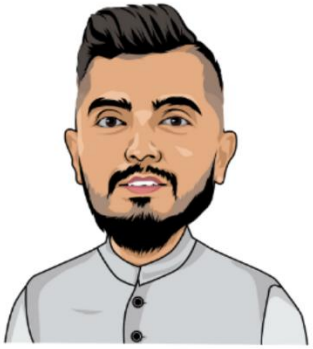
Conference Manager

General queries
T: +44 (0) 207 092 1070
E Anastasia.Beretsos@terrapinn.com

Edmond Rama

Business Development Manager

Sponsorship & Exhibition Opportunities
T: +44 (0) 207 092 1052
E: edmond.rama@terrapinn.com



TAYYAB ABBASI

Customer Services Manager

Assistance with Conference Registration
T: +44 (0)207 092 1210
E: tayyab.abbasi@terrapinn.com