World Drug Safety Europe Congress 2021

6-7th October 2021 – Hilton Amsterdam

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 **Online presentation: PV Industry Collaboration Update and Lessons**
Michael Braun-Boghos, Senior Director Safety Strategy, **Oracle Health Sciences**

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**
Online panellist: Deepa Venkataraman, Head of Global Patient Safety and Pharmacovigilance, **Summit Therapeutics**
Online panellist: 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**
Online panellist: 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: Kieran O'Donnell,** Principal Consultant**, Arriello**	11.20 **Chair: Rudi Scheerlinck,** Pharmacovigilance Risk Management Clinical Studies**, Galderma**	11.20 **Chair: Mark Perrott,** Managing Partner, **Axian Consulting Ltd**	11.20 **Chair: Magda Daudin,** Director, Pharmacovigilance QA Lead, **Idorsia**
11.25 **Quality. Cost. Speed. What really matters for PV automation adoption** **Natalia Vlcek,** EU QPPV**, Arriello**	11.25 **Online presentation: Drug safety in elderly patients** **Giovanni Furlan,** Safety Risk Lead Director**, Pfizer**	11.25 **Best practice in signal management across product life cycle** **Oleksandr Karpenko,** Principal Consultant**, Olexacon Limited**	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 **The impact of AI on PV systems** **Mircea Ciuca,** Therapeutic Area Head Global Clinical Safety and Pharmacovigilance**, CSL Behring**	11.45 **Online presentation: Implementation of complex risk minimisation measures** **Jackie Roberts,** Associate Vice President, Scientific Affairs, Governance**, Accord-UK Ltd**	11.55 **Online presentation: 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 **Online presentation: Leverage automation to surface safety signals more quickly and efficiently** **Andrew Rut,** CEO and founder**, MyMeds&**	12.05 **Tailored approaches towards benefit-risk evaluations** **Tjark Reblin,** Global Head Drug Safety and Risk Management**, Vifor Pharma**		11.55 **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 **Orchestrating PV process automation** **Martin Holm-Petersen,** CEO, **Insife**	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**		
12.45 **Networking Lunch**			
13.55 **Roundtables** **Roundtable 1: Exploring medicines safety in maternal health** **Belen Granell Villen,** Quality and Safety Policy Executive**, The Association of the British Pharmaceutical Industry** **+** **Roundtable 2: 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 3: 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 4: How to manage different QPPV roles and responsibilities to meet local requirements?** **Valentina Mancini,** Director Pharmacovigilance, EU QPPV**, Shionogi Europe** **+** **Roundtable 5: Meeting the requirements of case submission oversight from health authorities and business partners**			

Melanie Dullemond, PVQ Compliance Head, **Sanofi**

+

Roundtable 6: The use of digital tools to achieve risk management objectives

Mark Perrott, Managing Partner, **Axian Consulting Ltd**

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Roundtable 7: Adapting PV audit practices in a pandemic

Sharon Fabrizio, Head of Local PV Quality Oversight - Global Scope**, Sanofi**

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Roundtable 8: Quality. Cost. Speed - Discussing the results from Arriello's brand new transatlantic PV automation adoption survey

Natalia Vlcek, EU QPPV**, Arriello and Kieran O'Donnell,** Principal Consultant**, Arriello**

+

Roundtable 9: The evolving medtech regulatory landscape and post-market surveillance

Marian Daryouzeh, PV and Regulatory Expert, **EY and Alexandros Charitou,** Life Sciences Partner, **EY**

+

Roundtable 10: Current tech accelerators for your key PV business pains

Jesper Borgstrøm, Advanced Advisory Consultant – NNIT Drug Safety LS Advisory**, NNIT and Vicky Cabuntas,** Senior Consultant – NNIT Drug Safety and Clinical**, NNIT**

AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**QUALITY ASSURANCE AND COMPLIANCE**
14.50 **Chair: Kieran O'Donnell,** Principal Consultant**, Arriello**	14.50 **Chair: Amgad Shebl,** Director, Global Clinical Safety and Pharmacovigilance**, CSL Behring**	14.50 **Chair: Katrien Soleme,** Senior Director, Pharmacovigilance and Life Cycle Management Quality**, Bristol Myers Squibb**	14.50 **Chair: Mina Awad,** Pharmacovigilance Manager and QPPV, Middle East**, Kyowa Kirin International**
14:55 **Artificial Intelligence models to identify Adverse Events and Special Situations in the global and local scientific literature**	14:55 **Online presentation: Risk communication in Non-EU countries** **Marjan Dzeparoski,** RA and PV Manager**, Bionika Pharmaceuticals**	14:55 **Online presentation: Intelligence analysis in safety assessments**	14:55 **Online presentation: Transforming Safety with End-to-end PV Solutions**

Nicole Baker, CEO**, biologit and Bruno Ohana,** CTO**, biologit**		**Max Waschbusch,** TA Head Cardiovascular and Metabolism**, CSL Behring**	**Jen Markey,** Vice President, Safety Strategy, EU**, Veeva Systems**
15.15 **NLP-based AI for safety applications in Pharma** **Jane Reed,** Director, Life Sciences, **Linguamatics**	15.15 **The future of trust in pharmaceutical products and the role of safety** **Dave Nestor,** Director**, Deloitte UK**	15.15 **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**	15.25 **Online presentation: 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**
15:35 **Online presentation: Advancing Automation Adoption via Productionization** **Ramprasad Polana**, Associate Vice President, **ArisGlobal**	15:35 **PMSR for combination products in the US and its global impact** **Khaudeja Bano,** Executive Medical Director, Combination Product Safety Head**, Amgen**		
15.55 **Networking Break**			
AI + AUTOMATION	**RISK MANAGEMENT**	**SIGNAL DETECTION & MANAGEMENT**	**VACCINE SAFETY & PV SYSTEMS**
16.25 **Chair: Andrea Maulwurf,** Head of Corporate Pharmacovigilance, Global Leading Qppv**, Allergy Therapeutics**	16.25 **Chair: Valentina Mancini,** Director Pharmacovigilance, EU QPPV**, Shionogi Europe**	16.25 **Chair: Marian Daryouzeh,** PV and Regulatory Expert, **EY** and **Alexandros Charitou,** Life Sciences Partner, **EY**	16.25 **Chair: Deborah Layton,** Director of Epidemiology, Global Database Studies, Real World Solutions**, IQVIA**
16.30 **Online presentation: The use of robotic automation in PV** **Manoj Swaminathan,** Founder**, VigiServe Foundation**	16.30 **Are we really managing risks or just administrating the risks?** **Uwe Gudat,** Head of Clinical Safety and Pharmacovigilance Clinical	16.30 **Online presentation: Our transformation journey: From compliance driven to proactive safety surveillance**	16.30 **Monitoring the safety of the COVID-19 Vaccines using open source technology**

	Safety and Pharmacovigilance**, Fresenius Kabi SwissBioSim**	**Markus Krupp,** Associate Director, Safety Signal Management & Data Analytics**, Merck Healthcare**	**Lionel Van Holle,** Safety Surveillance Lead**, UCB and** Founder, **OpenSourcePV**
16.50 **Online presentation: 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 **Disruption and trends in E2E safety signals to labelling** **Marian Daryouzeh,** PV and Regulatory Expert, **EY and Alexandros Charitou,** Life Sciences Partner, **EY**	16.50 **Online presentation: Building a global centralized PV system from multiple independent PV system** **Margherita D'Antuono,** Corporate Pharmacovigilance Director, EU QPPV – UK QPPV**, ITALFARMACO S.P.A.**
17.10 **Online presentation: Utilising social media to support signal detection** **Juhaeri Juhaeri**, VP & Head, Epidemiology and Benefit-Risk, **Sanofi**	17.10 **Online presentation: Cross-functional benefit risk strategy, management and documentation** **Elian Khazneh,** Head of Medical Safety Operations**, Merck Healthcare**	17.10 **Online presentation: Harnessing AI to enhance signal detection capabilities** **Anupam Agarwal,** Vice President, Global Head of Drug Safety and PV**, Zogenix**	

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 **Online presentation: Pivoting Safety to Strategic Center with AI-Powerede Data Fabric**
Aman Wasan, Senior Vice President, Commercial Organization - Global, **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: Scott Chandler,** Global Head, Personalized Health Care (PHC) Safety, Product Development Safety**, Roche**	11.20 **Chair: Martijn van de Leur,** Head of Pharmacovigilance**, Biomapas**	11.20 **Chair: Sutirtha Mukhopadhyay,** Senior Risk Management Physician**, Boehringer Ingelheim**
11.25 **Considerations for an effective case assessment** **Daniela Di Cosmo,** Senior Pharmacovigilance Manager, Global Pharmacovigilance**, Ferring**	11.25 **Patient-centric approach to translational safety** **Scott Chandler,** Global Head, Personalized Health Care (PHC) Safety, Product Development Safety**, Roche**	11.25 **Pharmacovigilance Outsourcing – A trend and advantages with regulatory compliance** **Prashanth Bsb,** Director PV & QPPV**, Product Life Group**	11.25 **Exploring the regulatory landscape in Saudi Arabia, Oman, Egypt and UAE** **Syed Zaferuddin,** Global Pharmacovigilance Manager and QPPV**, Julphar**
11.45 **Examining the impact of Brexit on Pharmacovigilance activities** **Carmela Campana,** Pharmacovigilance Manager and EU QPPV**, Istituto Biochimico Italiano G. Lorenzini**	11.45 **Leveraging data from FDA/EMA drugs to support translational safety analytics: Developing an industry validated methodology for target safety risk assessment** **Catherine Noban**, Lead Product Manager – Content Assets, **Elsevier** 12.05 **Online presentation: Drug Repositioning: Conquering the Translational Barrier** **Nibedita Rath**, Scientific Director, **Open Source Pharma Foundation**	11.45 **Online presentation: Safety Challenges of a Vaccine in the Pandemic Time** **Jerome Premmereur,** Vice President Patient Safety, **Labcorp**	11.45 **Online presentation: Local Safety Representatives Challenges** **What is the 1st line Safety person facing?** **Mohamed Abdel Hady,** Sr. Manager, Global Patient Safety UAE**, Gilead Sciences**
12.45 **Networking Lunch**			

13.55 **Roundtables**

Roundtable 3 Track 1: Ensuring patient safety and data privacy within de-centralised trials
Vivienne van de Walle, Medical Director**, Precare Trial and Recruitment Research Centre**
+
Roundtable 4 Track 1: Exploring the critical paths of device safety in clinical investigations
Sylvie Bartus, Head of Clinical Safety, Surgical Structural Heart**, Edwards Lifesciences**
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Roundtable 5 Track 2: Exploring literature surveillance tools and processes
Paolo Voltolina, Director, Head of Regulatory Business Operations**, Lundbeck**
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Roundtable 6 Track 3: 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 7 Track 2 : Early detection of safety signals in clinical trials
Sutirtha Mukhopadhyay, Senior Risk Management Physician**, Boehringer Ingelheim**
+
Roundtable 8 Track 4: 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 9 Track 4: 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: Jacquelien Noordhoek**, President**, CF Europe**	14.55 **Chair: Muhammad Ashar Naeem,** Global Director Pharmacovigilance and Medical Affair**, Jamjoom Pharma**
15:00 **Experiences using machine translation to support global case in-take** **Adrian Maynier,** Head of Safety Systems**, UCB**	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 **Online presentation: Optimising early clinical investigations in cancer immunotherapy by increasing the translational value of non-clinical activities** **Estelle Marrer-Berger,** Toxicology Project Leader**, Roche**
15.20 **Online presentation: Common mistakes in case processing and useful tips to avoid them** **Aitzaz Khan,** Global Safety Lead**, Argenx**	15.20 **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**	15.20 **How can pharma improve healthcare for the patient: What does patient centricity really mean?** **Kristof Vanfraechem**, Founder and CEO, **Data For Patients and online presenter: Christine Von Raesfeld,** Founder**, People with Empathy**	15.20 **Online presentation: Biosimilar safety in the world of oncology** **Francesca Rollo,** Pharmacovigilance Analyst & Local Contact Point Deputy, **Viatris**
Closing remarks	*Closing remarks*	15.40 **What would personalised safety, delivered in a patient centric way, look like from a patient's perspective** **Jacquelien Noordhoek**, President**, CF Europe**	*Closing remarks*

16.00 **Close of conference**