







world DrugSafety congress

EUROPE 2014

Addressing the key challenges for safety professionals

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10-11 September 2014
Hotel Russell, London, UK

An event to wow

To achieve excellence in drug safety, pharma must balance the challenges that surround regulatory, resource and operational constraints while exploring new opportunities in safety strategy design and implementation. To succeed in this new environment, it is critical to understand how to design and implement a proactive patient-centric safety program and translate this into operational excellence in safety monitoring and response.

The World Drug Safety Congress will unite the biggest players in the sector who have trialled innovative processes, technologies and strategies and will share their experience with you. Take your place at the forefront of the new drug safety era and be part of these important discussions.

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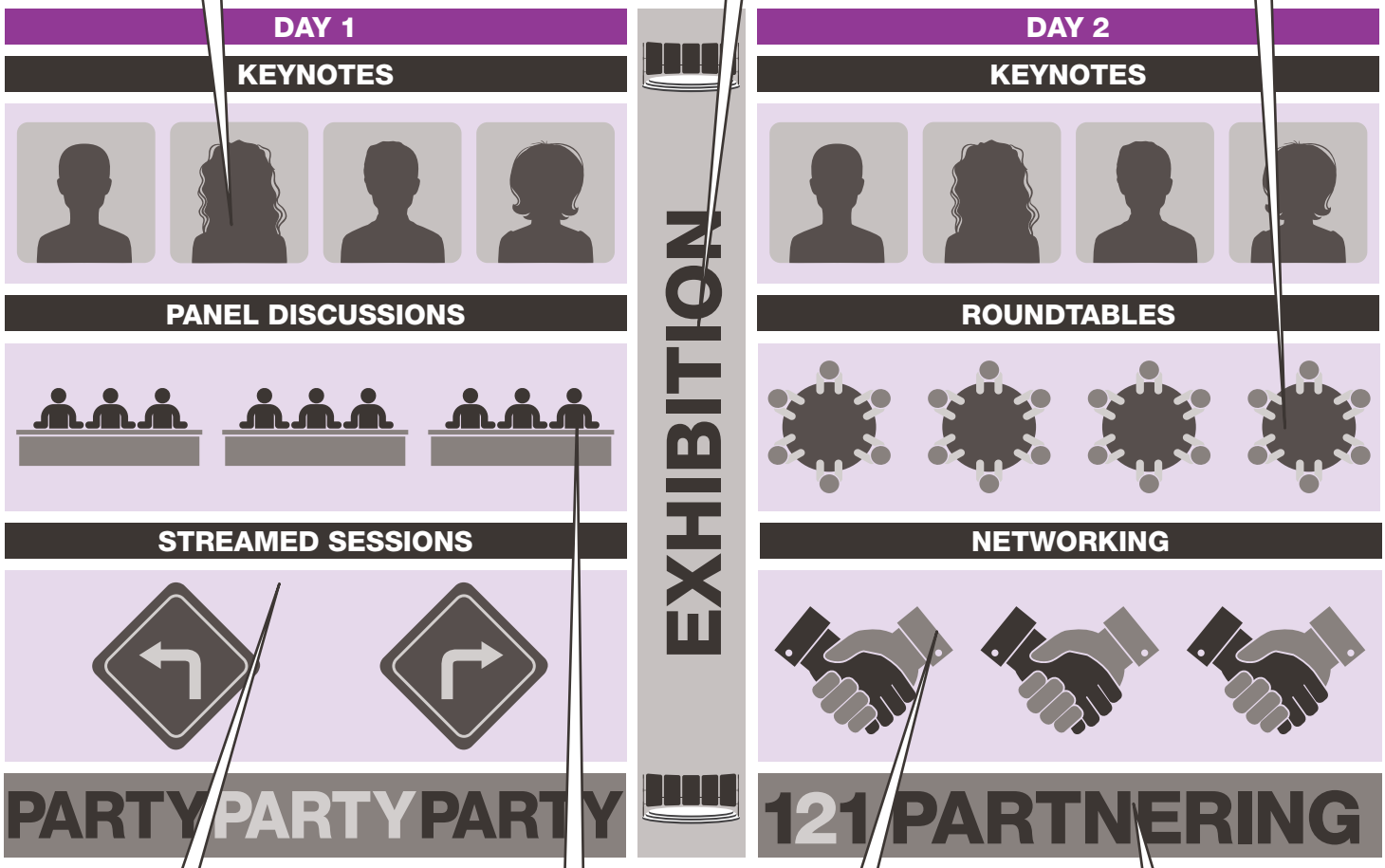


Create your own event agenda and attend focussed sessions most relevant to your business needs

Ask your burning questions to an expert panel

Meet new contacts and build on existing relationships

Use our networking app to arrange meetings before and during the event

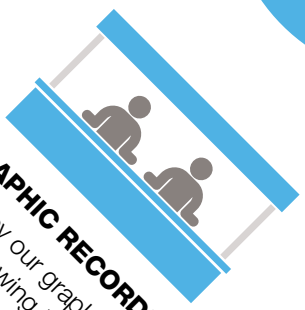
Learn, Partner, Innovate, Succeed

Prepare for the future drug safety landscape at World Drug Safety Congress Europe. Embrace key aspects of pharmacovigilance, signal detection, clinical safety, regulations and benefit risk management and take valuable insights back to your company. More interactive and engaging than ever before, put yourself in the centre of the conversations driving change in drug safety

MULTIPLE CONFERENCE TRACKS
Build the conference schedule that suits you.

PEER-TO-PEER ROUNDTABLES
Hosted interactive and intimate sessions to discuss and debate specific industry challenges

world DrugSafety congress EUROPE 2014



GRAPHIC RECORDER
Be inspired by our graphic recorders who will be drawing throughout the meeting and capturing the major themes, topics and discussion points

DEBATE
Quick fire arguments for the biggest game changer in the drug safety industry. Will it be a technology, process, company, person or regulation? Have your say and vote for your winner

For more information about the event, contact Alice Fairchild on
+44 (0) 207 608 7054 or email afairchild@healthnetworkcommunications.com

KEYNOTE SPEAKERS

Dr David Lewis
Global Head of Pharmacovigilance
Novartis Pharma AG

Dr David Lewis joined Drug Safety & Epidemiology at Novartis in March 2007. He had a variety of roles including EU QPPV and Global Head of Pharmacovigilance Systems and Data Management before promotion to Global Head of Pharmacovigilance in February 2011. He has experience of working in country affiliates and in a variety of global safety and risk management functions with both investigational and marketed products, as well as in roles concerned with systems and processes. He has also worked at Shire Pharmaceuticals and GSK and has a number of academic links, including being named Visiting Senior Fellow, Faculty of Health and Human Sciences, University of Hertfordshire.

András Lehoczki
Head of Drug Safety Data Operations
Grünenthal

András Lehoczki has been the Head of Drug Safety Data Operations at Grünenthal since 2013. His responsibilities include the compliant collection, verification, processing and reporting of safety information for the company's medicinal products. He is also responsible for the computerized systems within drug safety including the support for the setup and maintenance of related business processes. András has a M.Sc. degree in bioengineering and has five years experience in pharmacovigilance in various management positions.

Dr Lesley Wise
Vice President of Global PV Risk Management and Pharmacoepidemiology
Takeda

Dr Lesley Wise has responsibility for global risk management processes, benefit-risk assessment processes and implementation of risk management plans. She joined Takeda in 2010 after 9 years working at the MHRA as manager of the Pharmacoepidemiology Research Unit in the Vigilance and Risk Management of Medicines Division. In her current role, Lesley works closely with Pharmacovigilance, Regulatory and Medical Affairs colleagues to ensure a "joined up" approach to Benefit - Risk Management.

Mick Foy
Group Manager
MHRA

Mick Foy has been with the MHRA for 25 years and has worked in most areas of medicines regulation during that time. For the bulk of his career he has worked mainly in Pharmacovigilance and has also managed the General Practice Research Database (GPRD). Mick's main role is the development of Pharmacovigilance systems, ensuring the MHRA remains at the forefront in ensuring those systems capture the highest quality data from all concerned in medicines safety. It is his team that deliver the UK's drug safety monitoring programmes. Mick also leads the MHRA's Better Regulation of Medicines (BROMI) initiative, identifying ways to reduce the burden of regulation to deliver efficiencies to both the regulator and industry.

Dr John Solomon
Head of Pharmacovigilance - UK/Ireland
Sanofi

Dr John Solomon joined Sanofi in 2005 as the Head of Pharmacovigilance at the UK Affiliate. Qualified in medicine, John has worked for 16 years in the industry spending the last 12 of these years in clinical drug safety and post marketing drug surveillance activities. Other industry related experience includes pharmaceutical marketing and managing global clinical-drug safety programmes in the Pharma and CRO sectors respectively. John has over the years interfaced with UK Regulators on various Agency/industry initiatives including the Pharmacovigilance (PV) Better Regulation of Medicines Initiative (BROMI) work stream in the UK, the lay summary "Risk Management Plan", Forum on Benefit-Risk decision analysis and more recently the implementation of the New Pharmacovigilance legislation.

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Ana-Claudia Ianos
Associate Safety Risk Lead SEPGR, Safety Surveillance and Risk Management
Pfizer

Ana-Claudia is a physician working as an Associate Safety Risk Lead in Safety Surveillance and Risk Management at Pfizer. Her role entails performing proactive safety surveillance and risk management to effect product safety signal detection and evaluation, risk assessment and safety risk minimization. She provides pharmacovigilance expertise based on a thorough knowledge of Safety Risk Management internal and external environment, including applicable regulations and guidances, and well as with an understanding of scientific basis for therapies and drug-induced diseases.

Michael Ibara
Head of Pharmacovigilance Information Management
Pfizer

Michael has throughout his career focused on the interface between business, technology and knowledge as it applies to pharmacovigilance and related disciplines. Michael received his Pharm.D. degree from the University of Michigan and completed a Fellowship in Drug Research and Development with Burroughs Wellcome, Inc. and the University of North Carolina. At Pfizer, Michael has lead the design and roll-out of an electronic submissions system and has managed the implementation of large-scale safety technologies. Several years ago he established a function to concentrate on the information management needs of the safety organization, and this lead him to research the possibility of improving public health through new approaches to pharmacovigilance.

John Freeman
Corporate Vice-President, Head of Global Drug Safety & Risk Management
Celgene Corporation

John has a background in Clinical Pharmacology and Law, and is responsible for Celgene's global pharmacovigilance and risk management programs. John has worked in the field of pharmacovigilance since 1986 with roles in Glaxo and Amgen. In his present role within Celgene, John heads the global pre- and post-marketing pharmacovigilance of products that includes thalidomide and its analogues – an extension of that responsibility is the oversight of the company's risk management programs.

XingMin Qiu
Associate Director, Associate Safety Risk Lead Safety Surveillance and Risk Management Safety, Established Products & Generics Regulatory
Pfizer

XingMin Qiu has more than ten years of working experience with the multi-national pharmaceutical industry in China, with a variety of roles in clinical development, drug safety and pharmacovigilance, and medical affairs. Currently she is responsible for safety surveillance and risk management to effect dozens of products safety signal detection and evaluation, risk assessment, and safety risk minimization. She was invited to present on pharmacovigilance in the universities and chaired the DIA China safety sessions.

Peter Verdru
Vice President Drug Safety Sciences, Drug Safety
UCB Pharma S.A.

After 4 years of clinical practice as Neurologist, Dr. Verdru joined UCB. Positions he held include a variety of roles with increasing responsibilities within Medical Affairs and Clinical Development, both in Belgium and the USA. He joined Drug Safety in 2010 as Head of US Drug Safety. He now is Vice President Safety Sciences, responsible for Surveillance Management, Epidemiology, Benefit Risk Management and Process Innovation.

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DAY ONE

WEDNESDAY 10TH SEPTEMBER

8.00 **Registration opens**

9.00 **Opening remarks from chair**

PROACTIVE DRUG SAFETY CULTURE

9.20 How to truly embrace a proactive drug safety culture
Dr John Solomon MD, PDipM, MCO, Head of Pharmacovigilance, UK & Ireland, **Sanofi**

EUROPEAN PHARMACOVIGILANCE LEGISLATION

9.50 European pharmacovigilance legislation – review of key module developments
Mick Foy, Group Manager - Vigilance Intelligence and Research Group, Vigilance and Risk Management of Medicines, **MHRA**

10.15 Panel discussion: Operational implications for integration of the EU pharmacovigilance legislation
Chair: Marcin Marciniak, Senior Director Drug Safety & Pharmacovigilance/Deputy QPPV, **Preglem**

Sue Rees, BSc (Hons) MSc HonFPIPA, Head of International Pharmacovigilance & QPPV, **Amgen**

Livia Stankovics, Regulatory Affairs & Pharmacovigilance Director, **Sanofi Aventis**

Mick Foy, Group Manager - Vigilance Intelligence and Research Group, Vigilance and Risk Management of Medicines, **MHRA**

10.50 **Morning refreshments & speed networking**

INNOVATION IN DRUG SAFETY

11.45 Social media and mobile reporting: WEB-RAdR - a new dimension for pharmacovigilance?
Dr David Lewis, Global Head of Pharmacovigilance, Visiting Senior Fellow, School of Life and Medical Sciences, University of Hertfordshire, Drug Safety & Epidemiology, **Novartis Pharma AG**

12.10 Panel discussion: Innovative opportunities to improve the pharmacovigilance of patient support programmes & social media

Dr David Lewis, Global Head of Pharmacovigilance, **Novartis Pharma AG**

Michael Ibara, Head of Pharmacovigilance Information Management, **Pfizer**

Mick Foy, Group Manager - Vigilance Intelligence & Research Group, Vigilance Risk Management of Medicines, **MHRA**

12.45 **Lunch**

SAFETY DATA COLLECTION AND MANAGEMENT

1.55 Chair's opening remarks: **Sabine Richter,** Vice President Safety & Risk Management, **PRA International**

2.00 Signal detection and management strategies for mature products: challenges, expertise requirements and strategies for success
Ana-Claudia Ianos, MD, Associate Safety Risk Lead SEPGR, Safety Surveillance and Risk Management, **Pfizer**

2.25 Collection of safety data through EDC systems: Challenges & solutions
Josee Moon, Senior Safety Scientist, **PRA International**

2.50 Recent experiences: OMOP and EUADR
Speaker to be confirmed

OPERATIONAL EXCELLENCE IN DRUG SAFETY

1.55 Chair's opening remarks

2.00 Organisational excellence in drug safety & risk management
John Freeman M.Sc., LLB (Hons), B.Sc.(Hons), DipClinSci, Corporate Vice-President, Head of Global Drug Safety & Risk Management, **Celgene Corporation**

2.25 Next generation PV – achieving operational excellence to ensure compliance and quality
Boris Jankowski, Director, Solutions Architecture Services, **Sciformix**

2.50 Pharmacovigilance compliance strategies
Noha Kassem, PhD, Senior Director,Quality in Global Patient Safety, **Lilly**

3.15 **Afternoon refreshments**

3.50 Human factors in pharmacovigilance tasks: what can we learn from other industries?
Alan Hochberg, Process Development Leader and DSC Office, **F. Hoffmann-La Roche**

4.15 Achieving pharmacovigilance excellence through outsourcing
Véronique Basch, PharmD, Executive Director, Global Pharmacovigilance, **UBC**

4.40 **Debate: The biggest game changer in the drug safety industry is?**

5.05 **Party**

DAY TWO THURSDAY 11TH SEPTEMBER

9.00 Innovation in pharmacovigilance
Logesvaran Yogendran, Vice President and QPPV, **Johnson & Johnson**

9.25 Panel Discussion: Where are the key opportunities to innovate and improve drug safety for patients?

Logesvaran Yogendran, Vice President and QPPV, **Johnson & Johnson**

Chetan Chinmaya Shatapathy, Medical Director – Pharmacovigilance, **Takeda Development Centre Europe**

Dr Sumit Munjal, Consultant Physician, Global Pharmacovigilance Director & EU Medical Advisor, Oncology, **Takeda Oncology: Millennium Pharmaceuticals**

Balwant Heer, VP, Global Head, Product Safety & Risk Management, QPPV EEA, **Mylan**

10.00 Big data & drug safety
Speaker to be confirmed

10.20 **Morning refreshments**

11.00 **PEER TO PEER ROUNDTABLES**

1 Pharmacovigilance inspections best practice: Internal readiness and methodology
Dr John Solomon MD, PDipM, MCO Head of Pharmacovigilance UK & Ireland, **Sanofi**

2 Signal management, analysis and evaluation
Dr Michael Lusiola, PharmD, MRPS, MICR Patient Safety Senior Scientist / Safety Management Team Leader - Oncology TA, **AstraZeneca**

3 Implementing the voice of the patient in risk management and drug safety
Lisa Chamberlain James, PhD, Senior Partner, **Trilogy Writing and Consulting**

4 Opportunities and hurdles for drug safety in the digitised world
Speaker to be announced

12.00 **Lunch**

BENEFIT RISK MANAGEMENT STRATEGIES

1.00 The changing face of benefit risk management
Lesley Wise, Vice President, Global PV Risk Management and Pharmacoepidemiology Pharmacovigilance, **Takeda Development Centre Europe**

1.25 Risk minimisation measures: Selection of tools and evaluation of effectiveness
Dr Michael Forstner, Head Pharmacovigilance Europe, **Boehringer Ingelheim**

1.50 Relative benefit risk management: Challenges for established products in light of new product influence
Peter Verdru, VP Drug Safety Sciences, Drug Safety, **UCB Pharma S.A.**

2.15 Safety, pharmacoepidemiology and observational research in practice
Anca Miclea, Senior Specialist Medical Safety and Epidemiology, Global Pharmacovigilance Established Products, **Abbvie**

2.40 **Afternoon refreshment**

GLOBAL SAFETY SNAPSHOT

3.10 Process excellence achievements and simple solutions towards efficiency in operations
András Lehoczki, Director Global Drug Safety Head Data Operations, **Grünenthal GmbH**

3.35 International insight: review and impact of key regional drug safety developments across Asia Pacific

Jessica Thongcharen, PV Manager - Asia Pacific, **Takeda** Singapore

Dr Mazhar Maruf, Regional Head- Asia Pacific, Depart of Global Pharmacovigilance, **Glenmark** India

XingMin Qiu, Associate Director, Associate Safety Risk Lead Safety Surveillance and Risk Management Safety, Established Products & Generics Regulatory, **Pfizer** China

4.30 **Close of conference**