International Society of Pharmacovigilance

Committed to safer use of medicines worldwide

ISoP-DSRU mid-year training 2022

Programme

Beyond spontaneous reporting: integrating data from multiple sources to ensure medicines safety

	Event Day-1	Event Day-2
UK time - UTC+1	**Tuesday May 10**	**Wednesday May 11**
	Session 1A	Session 2A
	Session 1B	Session 2B
	Session 1C	Session 2C
	Session 1D	

On-line symposium, May 10

Day 1- Tuesday, May 10 **Beyond spontaneous reporting: integrating data from multiple sources to ensure medicines safety**		
Session UTC+1	Session title	Speakers
0900 - 0910	**Welcome and Introduction** Rebecca E Chandler (ISoP Vice-President, Coalition for Epidemic Preparedness Innovations) and Saad Shakir (Director, Drug Safety Research Unit)	
Session 1.A 0910-1030	**Causality - complexities and challenges** *Chairs: Rebecca E Chandler (ISoP Vice-President, Coalition for Epidemic Preparedness Innovations) and Saad Shakir (Drug Safety Research Unit)*	
1.A.1 0910-0950	Causality, complexity and evidence in health sciences	**Elena Rocca** Oslo Met University, Norway
1.A.2 0950-1030	When evidence of causality contradicts conventional wisdom: Non-specific effects of vaccines and the Bandim Health Project	**Christine Stabell Benn** University of Southern Denmark
1030-1100	*Break*	

Session 1.B 1100-1355	**Maximising potential of established sources in pharmacovigilance: spontaneous reporting systems and observational studies** *Chairs: Mira Harrison-Woolrych (ISoP President) and Rebecca E Chandler (ISoP Vice-President, Coalition for Epidemic Preparedness Innovations)*	
1.B.1 1100-1125	Can incorporation of clinical observations improve quantitative signal detection?	**Eugene van Puijenbroek** Netherlands Pharmacovigilance Centre Lareb
1.B.2 1125-1150	Using network analysis for better signal detection in pharmacovigilance	**Mátyás Pétervári** Semmelweiss University, Hungary
1.B.3 1150-1215	Contribution of observational studies to understanding of drug safety issues	**Saad Shakir** Director, Drug Safety Research Unit (DSRU), UK
1215-1315	*Lunch*	
Session 1.B.4 1315-1335	**Communicating epidemiology to the public** Experiences from the EMA in communicating COVID-19 vaccine safety	**Priya Bahri** European Medicines Agency
1.B.5 1335-1355	Panel discussion	
1355-1400	*Break*	
Session 1.C 1400-1530	**The challenges of leveraging safety data from clinical trials** *Chairs: Deirdre McCarthy (ISoP Secretary-General, AlloVir) and Elizabeth Lynn (Drug Safety Research Unit)*	
1.C.1 1400-1420	Safety data from published clinical trials - just how much is missing?	**Su Golder** Department of Health Sciences, University of York, UK
1.C.2 1420-1440	How can unpublished data inform the safety profile of a medicine?	**Igho J Onakpoya** Centre for Evidence-Based Medicine, Oxford, UK
1.C.3 1440-1500	The potential contributions of electronic case report forms - when you can get them	**Tom Jefferson** University of Oxford, Cochrane, UK
1.C.4 1500-1530	Panel discussion	
1530-1600	*Break*	
Session 1.D 1600-1730	**Contributions from the field of pharmacogenomics** *Chairs: Mónica Tarapués (ISoP Advisory Board member, Central University of Ecuador) and Jan Petracek (ISoP Advisory Board member, Institute of Pharmacovigilance)*	
1.D.1 1600-1620	Experiences of Swedegene, coupling pharmacovigilance and pharmacogenomics	**Mia Wadelius** Uppsala University, Sweden
1.D.2 1620-1640	From a case series to public health impact using pharmacogenomics in Eritrea	**Mulugeta Russom** National Medicines and Food Administration, Ministry of Health, Asmara, Eritrea
1.D.3 1640-1700	Moving pharmacovigilance from signal detection to problem solving: Canadian Pharmacogenomics Network for Drug Safety	**Bruce Carleton** University of British Columbia, Canada
1700-1730	**Questions and Closing remarks**	
End of Day 1		

Online symposium, May 11

Day 2- Wednesday, May 11 **Beyond spontaneous reporting: integrating data from multiple sources to ensure medicines safety**		
0900 -0915	**Welcome back and housekeeping**	
Session 2.A 0915-1100	**Integrating safety data to meet the needs of different stakeholders** *Chairs: Manal Younus (ISoP Advisory Board member, Iraqi Pharmacovigilance Center) and Miranda Davies (Drug Safety Research Unit)*	
2.A.1 0915-1000	Formal Benefit-Risk Evaluation: a case study	**Miranda Davies** Chief Medical Officer, Drug Safety Research Unit (DSRU), UK
2.A.2 1000-1020	Integrating data for implementation into clinical practice	**Francois Montastruc** Department of Clinical and Medical Pharmacology Toulouse, TMBI, Univ. Toulouse, France
2.A.3 1020-1040	Integrating safety data from the perspective of industry	**Maribel Salas** Epidemiology, Clinical Safety and Pharmacovigilance, Daiichi Sankyo, Inc. USA
2.A.4 1040-1100	Towards a more patient-centered approach to medicines safety	**Suzanne B. Robotti** Founder, MedShadow Foundation Drug Safety and Risk Management FDA Advisory Committee
1100-1130	*Break*	
Session 2.B 1130-1315	**Real-world data to inform on the safety of the COVID-19 vaccines** *Chairs: Angela Caro Rojas (ISoP Advisory Board member, Pontificia Universidad Javeriana, Colombia) and Zhang Li (ISoP Advisory Board member, Dongfang Hospital affiliated to Beijing University of Chinese Medicine)*	
2.B.1 1130-1150	AEFI/AESI Sentinel Surveillance Network for the COVID-19 vaccines by Pan American Health Organisation	**Ivonne Solarte** PAHO
2.B.2 1150-1210	Integrating pharmacovigilance and clinical pharmacology to unravel myocarditis after COVID-19 vaccination	**Alison Yeomans** Drug Safety Research Unit (DSRU), UK
2.B.3 1210-1230	Experiences from the AU-3S project on monitoring COVID-19 vaccines	**Victoria Nambasa** AU-3S Programme: officer safety
2.B.4 1230-1250	Experience using a social media survey to explore menstrual disorders after COVID-19 vaccination	**Katharine Lee** Washington University School of Medicine, Division of Public Health Sciences, USA
2.B.5 1250-1315	Panel discussion	
1315-1400	*Lunch*	
Session 2.C 1400-1600	**The use of big data in pharmacovigilance** *Chairs: Mira Harrison-Woolrych (ISoP President) and Saad Shakir (Director, Drug Safety Research Unit)*	
2.C.1 1400-1430	The role of big data for postmarketing surveillance of medicines and vaccines: a European perspective	**Gianluca Trifirò** University of Verona, Italy
2.C.2 1430-1500	No population left behind: Improving paediatric drug safety using informatics and systems biology	**Nicholas Tatonetti** Columbia University Data Science Institute, USA
2.C.3 1500-1530	Panel Discussion	
	Wrap up	
End of the Symposium and training		