International Society of Pharmacovigilance

Committed to safer use of medicines worldwide

ISoP Mid-Year Symposium 2024

The value of real-world data for ensuring patient safety

Barcelona, Spain 3-4 June 2024

MEETING VENUE:

SANT PAU RECINTE MODERNISTA
Fundació Hospital Santa Creu i Sant Pau
Sant Antoni Maria Claret, 167. 08025 Barcelona

Meeting room: Pau Gil Room

Inquiries, phone
+44 (0) 20 3256 0027
www.isoponline.org
administration@isoponline.org
Contact: Sophie Spence
+44 777 306 2841 (mobile)

Day 1- Monday, June 3

Real-World Evidence (RWE)

Session	Session title	Speaker
08.30-09.00	Registration	
Session 1 09.00-10.30	**Leveraging database networks for monitoring vaccines and medicines** Chair: Gianluca Trifiró, University of Verona, Italy	
1.A 09.00-09.10	Welcome and Introduction to the symposium Felipe Villalobos, IDIAP Jordi Gol, Spain, Angela Caro-Rojas *(ISoP President),* Josep Basora *(IDIAP Jordi Gol),* Anna Berenguera *(IDIAP Jordi Gol),* and Marco Tuccori *(University of Pisa, Italy)*	
1.B 09.10.09.35	Use of Real-World Evidence in medicines regulation: how RWE is transforming regulatory decision making?	Patrice Verpillat *European Medicines Agency (EMA) (Netherlands)*
1.C 09.35-10.00	Harmonization of safety assessments of vaccines and medicines from SPEAC to VAC4EU/ConcePTION	Miriam Sturkenboom *University Medical Center Utrecht*

		(Netherlands)
1.D 10.00-10.25	Regulatory driven studies in the European landscape	Susana Perez-Gutthann *RTI Health Solutions (Spain)*
10.25-10.30	Questions and discussion	
10.30-11.00	*Coffee Break and networking*	
Session 2 **11.00-12.30**	**Insights into Real-World Evidence to improve pharmacovigilance** Chair: Felipe Villalobos, IDIAP Jordi Gol, Spain	
2.A 11.00-11.25	Real-World Data to improve pharmacovigilance: perspective from a regulatory agency	Edurne Lázaro Bengoa *Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) (Spain*)
2.B 11.25-11.50	Using Real-World Data for signal validation and prioritisation: experiences from a European network study	Judith Brand *Uppsala Monitoring Centre (Sweden)*
11.50-12.00	Questions and discussion	
2.C 12.00-12.15	Abstract presentation: #40 TheShinISS-Vax: post-marketing active surveillance of the safety of COVID-19 and influenza vaccines in Italy	Stefania Spila-Alegiani and Marco Massari *National Institute of Health (Italy)*
2.D 12.15-12.30	Abstract presentation: #55 A way towards reliable research: mapping data quality assessments in multi-database pharmacoepidemiologic studies	Judit Riera-Arnau *University Medical Center Utrecht (UMCU) (Netherlands)*
12.30-13.30	*Lunch*	

International Society of Pharmacovigilance

Committed to safer use of medicines worldwide

Session 3 **13.30-15.00**	**Quality in signal detection** Chair: Martín Solorzano, IDIAP Jordi Gol, Spain	
3.A 13.30-13.55	Ensuring appropriate quantitative signal detection: Routine Use, Challenges, and Industry Insights	Vijay Kara, *GSK (UK)* Eric Smith, *GSK (USA)*
3.B 13.55-14.20	The REporting of A Disproportionality analysis for drUg Safety signal detection using individual case safety reports in PharmacoVigilance (READUS-PV): development and statement	Francesco Salvo *ISoP Board Member, University of Bordeaux (France)*
14.20-14.30	Panel discussion	
3.C 14.30-14.40	Abstract presentation: #7 Using Real-World Data (RWD) for Rapid Safety Signal Assessment	Vaishali Patadia *AMGEN (USA)*
3.D 14.40-14.50	Abstract presentation: #51 Antipsychotics and risk of relevant weight gain in naïve patients: a nested Case-Control study from the ICARO study	María Sáinz Gil *Universidad de Valladolid (Spain)*
14.50-15.00	Questions and discussion	
15.00-15.30	*Coffee Break and networking*	
Session 4 **15.30-17.00**	**Pharmacovigilance in a changing world: innovation, collaboration, and regulation** Chair: Marco Tuccori, University of Pisa, Italy	
4.A 15.30-15.55	Adapting to change through innovation and collaboration	Linda Härmark *The Netherlands Pharmacovigilance Centre Lareb*
4.B 15.55-16.20	ADR coding in pharmacovigilance: usefulness of generative AI and large language models	Louis Létinier *Synapse Medicine (France)*
16.20-16.30	Questions and discussion	

4.C 16.30-16.45	Abstract presentation: #17 Integrating Risk Minimization Measures of Medications into Hospital Information Systems: Insights from three Hospitals in Saudi Arabia	Wed AlGhannam *Saudi Food and Drug Authority (Saudi Arabia)*
4.D 16.45-17.00	Abstract presentation: #25 Analysis of the teaching-learning process of pharmacovigilance in Portugal	Margarida Perdigão *University of Evora (Portugal)*

End of Day 1

Day 2- Tuesday, June 4 **Primary care and clinical aspects of pharmacovigilance**		
	Welcome back and housekeeping	
Session 5 **09.00-10.30**	**Pharmacogenomics and Personalized Medicine: Better-adapted Medicine and Pharmacovigilance** Chair: Linda Härmark, The Netherlands Pharmacovigilance Centre Lareb	
5.A 09.00-09.40	The promise of pharmacogenomics: where are we now and where are we going?	Sir Munir Pirmohamed *University of Liverpool (UK)*
5.B 09.40-10.00	Pharmacovigilance challenges in personalized medicine	Caridad Pontes *Hospital de la Santa Creu I Sant Pau (Spain)*
5.C 10.00-10.20	The Yellow Card Biobank: Strengthening Pharmacovigilance through Pharmacogenomics	Jessica Wright *Medicines and Healthcare products Regulatory Agency (MHRA) (UK)*
10.20-10.30	Questions and discussion	
5.D 10.30-10.40	**ISoP Fellowship - What is an ISoP fellow?**	Angela Caro-Rojas *ISoP President* Santiago Schiaffino, *FISoP*

International Society of Pharmacovigilance

Committed to safer use of medicines worldwide

10.40-11.00	*Coffee Break and networking*	
Session 6 **11.00-12.30**	**Strengthening patient safety: Integrating pharmacovigilance in Primary Care** Chair: Ghita Benabdallah, ISoP Board member, Centre Anti poison et de Pharmacovigilance du Maroc, Morocco	
6.A 11.00-11.25	Pharmacovigilance and Patient Safety Strategy in Catalonia	Clara Pareja Rossell *Health Department, Generalitat de Catalunya (Spain)*
6.B 11.25-11.50	Pharmacovigilance in Primary Care: Challenges and Opportunities	María José Peñalver Jara *Pharmacovigilance Centre of Murcia (Spain)*
6.C 11.50-12.15	Antimicrobial Resistance and Pharmacovigilance – Mapping the Venn Diagram	Ryan Walker *The Global Health Network, University of Oxford (UK)*
12.15-12.30	Questions and discussion	
12.30-13.30	*Lunch*	
Session 7 **13.30-15.00**	**Pharmacovigilance and vaccines** Chair: Gianmarco Di Mauro, TEAMIT, Spain	
7.A 13.30-13.55	The Role of the European Medicines Agency in the Safety Monitoring of COVID-19 Vaccines and Future Directions in Enhancing Vaccine Safety Globally	Irina Caplanusi *European Medicines Agency (EMA) (The Netherlands)*
7.B 13.55-14.20	Effectiveness of one dose of MVA-BN vaccine against mpox: a multicountry target trial emulation study	Clara Suñer *Fight Infections Foundation (Spain)*
14.20-14.30	Questions and discussion	

7.C 14.30-14.45	Abstract presentation: #43 Integrating spontaneous reporting with real world data for signal detection processing: the example of acquired haemophilia A and COVID-19 Vaccines	Emiliano Cappello *University of Pisa (Italy)*
7.D 14.45-15.00	Abstract presentation: #11 GP consultations for menstrual disorders after COVID-19 - a self-controlled cohort study based on routine healthcare data from the Netherlands	Rana Jajou *The Netherlands Pharmacovigilance Lareb*
15.00-15.30	*Coffee Break and networking*	
Session 8 **15.30-17.00**	**Patient communication and pharmacovigilance education** Chair: Angela Caro-Rojas, ISoP President, Colombia	
8.A 15.30-15.55	Pharmacovigilance in the age of fake news	Antònia Agustí *Hospital Universitari Vall d'Hebron, Barcelona (Spain)*
8.B 15.55-16.20	How to improve the impact of communication in pharmacovigilance	Agnes Kant *The Netherlands Pharmacovigilance Centre Lareb*
8.C 16.20-16.45	Patient behaviour in response to medicine safety communications	Marco Tuccori *University of Pisa (Italy)*
16.45-17.00	Questions and discussion	
	Closing remarks and End of the Symposium	