International Society of Pharmacovigilance

Committed to safer use of medicines worldwide

Mid-Year Symposium 2023

Pharmacovigilance: where science meets clinical practice

Leiden, Netherlands 1-2 June, 2023

RIJKSMUSEUM BOERHAAVE
Lange St. Agnietenstraat 10
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Meeting room: congresruimte

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Day 1- Thursday, June 1

The role of clinical pharmacology, pharmacoepidemiology and pharmacovigilance in collecting and analysing safety information

Session	Session title	Speaker
08.30-09.00	Registration	
Session 1 09.00-10.30	How can Pharmacovigilance, Epidemiology and Clinical Pharmacology collaborate to decrease harm of medicines? Chair: Linda Härmark (*The Netherlands Pharmacovigilance Centre Lareb)*	
1.A 09.00-09.15	Welcome and Introduction to the conference Linda Härmark *(The Netherlands Pharmacovigilance Centre Lareb)*, Eugène van Puijenbroek (*The Netherlands Pharmacovigilance Centre Lareb)*, Francesco Salvo (*ISoP Board member, University of Bordeaux),* and Marco Tuccori *(ISoP Scientific Board co-chair, University Hospital of Pisa)*	

1.B 09.10-09.35	How I translate pharmacovigilance data to my patients: balancing compliance, safety, and efficacy	Gerard Rongen *European Association for Clinical Pharmacology and Therapeutics (EACPT)*
1.C 09.35-10.00	The synergy between Pharmacovigilance, Clinical Practice, and Epidemiology from an epidemiological perspective	Tobias Gerhard *International Society for Pharmacoepidemiology (ISPE)*
1.D 10.00-10.25	The synergy between Pharmacovigilance, Clinical Practice, and Epidemiology from a Pharmacovigilance perspective	Daniel Morales *European Medicines Agency (EMA)*
10.30-11.00	*Coffee Break and networking*	
Session 2 11.00-12.30	Do we need to re-think the concept of causality? Chair: Rebecca Chandler *(Coalition for Epidemic Preparedness Innovations, Sweden)*	
2.A 11.00-11.30	Causality assessment, what's in it for pharmacovigilance	Eugène van Puijenbroek *The Netherlands Pharmacovigilance Centre Lareb*
2.B 11.30-12.00	Dispositions and Causality Assessment in Pharmacovigilance	Elena Rocca *Oslo Met University*
12.00-12.30	Panel discussion with the participation of: Eugène van Puijenbroek (The Netherlands Pharmacovigilance Centre Lareb), Elena Rocca (Oslo Met University), David Lewis (Novartis-TBC), Saad Shakir (DSRU), Daniele Sartori (UMC)	
12.30-13.30	*Lunch*	
Session 3 13.30-15.00	Using information from other sources in pharmacovigilance Chair: Eugène van Puijenbroek (*The Netherlands Pharmacovigilance Centre Lareb)*	
3.A 13.30-13.55	The use of real-world evidence in pharmacovigilance	Helga Gardarsdottir *Utrecht University (Netherlands)*
3.B 13.55-14.20	Detection of adverse drug reactions using hospital discharge database	Jean-Luc Faillie *CHU Montpellier, Montpellier University, Faculty of Medicine (France)*

3.C 14.20-14.45	Enhancing Yellow Card data to improve signal detection at the MHRA	Sarah Vaughan *Medicines and Healthcare products Regulatory Agency (MHRA) (UK)*
3.D 14.45-14.52	Abstract presentation: #10 Electronic health records as an innovative additional resource to the spontaneous reporting system for optimizing drug-safety	Willem van der Weg *The Netherlands Pharmacovigilance Centre Lareb*
3.E 14.52-14.59	Abstract presentation: #38 Sensitivity and specificity of International Classification of Diseases (ICD 10) codes to identify medication-related hospital admissions	Daniala L. Weir *Utrecht University (Netherlands)*
15.00-15.30	*Coffee Break and networking*	
Session 4 15.30-17.00	Innovative methods in pharmacovigilance Chair: Sarah Vaughan *(MHRA)*	
4.A 15.30-15.55	Dealing with Disproportionality Analysis in the post-Covid era	Sara Vidlin *Uppsala Monitoring Centre (Sweden)*
4.B 15.55-16.20	Knowledge integration for case assessment and prioritisation	Marco Tuccori *University Hospital of Pisa (Italy)*
4.C 16.20-16.45	Future of pharmacovigilance: how artificial intelligence will change our work	Francesco Salvo *University of Bordeaux (France)*
4.D 16.45-16.52	Abstract presentation: #28 Introducing a digital co-worker to make report handling more efficient - Robotic Process Automation (RPA) at the Swedish Medical Products Agency	Maria Larsson *Swedish Medical Products Agency*
4.E 16.52-16.59	Abstract presentation: #39 Refining disproportionality for signal detection in pregnant women: the case study of preeclampsia-eclampsia and antidepressants	Laurent Chouchana *Centre Régional de Pharmacovigilance et d'information sur le médicament - Hopital Cochin, APHP. Centre – Université Paris Cité, France*
17.00-18.00	European Chapter session	
18.00-19.00	Complimentary networking drinks reception	

Day 2 – Friday, June 2 **Implementing pharmacovigilance in clinical practice**		
	Welcome back and housekeeping	
Session 5 09.00-10.30	Implementing pharmacovigilance in clinical practice Chair: Francois Montastruc *(Faculty of Medicine and Toulouse University Hospital, France)*	
5.A 09.00-09.25	Safety of JAK inhibitors	Christophe Richez *Bordeaux University (France)*
5.B 09.25-09.50	Are ADRs predictable?	Henk-Jan Guchelaar *Leiden University Medical Center (Netherlands)*
5.C 09.50-10.15	The SYMPRO app to monitor side effects of cancer drugs: primary and secondary use of data	Corina van den Hurk *Netherlands Comprehensive Cancer Organisation (IKNL)*
5.D 10.15-10.22	Abstract presentation: #9 Impact of TTS reports associated with Vaxzevria and Jcovden on national COVID-19 vaccination policies	Ella van Vliet *Dutch National Institute for Public Health and the Environment (Netherlands)*
5.E 10.22-10.29	Abstract presentation: #34 Cohort Event Monitoring of Safety of COVID-19 Vaccines in People with Prior SARS-CoV-2 Infection	Francesco Ciccimarra *University of Verona (Italy)*
10.30-11.00	*Coffee Break and networking*	
Session 6 11.00-12.30	The role of patients in pharmacovigilance Chair: Florence van Hunsel *(The Netherlands Pharmacovigilance Centre Lareb)*	
6.A 11.00-11.25	Patient involvement in the safe use of drugs, CIOMS XI	Lembit Rägo *Council for International Organizations of Medical Sciences (CIOMS)*
6.B 11.25-11.50	Role of patients in medicines safety monitoring: a perspective from the Patient and Consumer Working Party	Kaisa Immonen *European Medicines Agency (EMA)*
6.C 11.50-12.15	Engaging Patients via Online Healthcare Fora: Three Pharmacovigilance Use Cases	Vijay Kara *GSK (UK)*
6.D 12.15-12.22	Abstract presentation: #25 What characterises the course of adverse drug reactions from a patient's perspective?	Jette van Lint *The Netherlands Pharmacovigilance Centre Lareb*

6.E 12.22-12.29	Abstract presentation: #12 Item selection for a measurement instrument for the patient-reported burden of adverse drug reactions	Leanne Kosse *The Netherlands Pharmacovigilance Centre Lareb*
12.30-13.30	*Lunch*	
Session 7 13.30-15.00	What do stakeholders need from pharmacovigilance? Chair: Agnes Kant *(The Netherlands Pharmacovigilance Centre Lareb)*	
7.A 13.30-13.55	Pharmacovigilance and the outside world: a press perspective	Maarten Keulemans *de Volkskrant*
7.B 13.55-14.20	What do medical doctors need with regards to pharmacovigilance?	Teun van Gelder *Leiden University Medical Center (Netherlands)*
7.C 14.20-14.45	Impact of pharmacovigilance: take stakeholders' needs into account	Agnes Kant *The Netherlands Pharmacovigilance Centre Lareb*
14.45-15.00	Panel discussion with the participation of: Maarten Keulemans (de Volkskrant*),* Teun van Gelder (Leiden University Medical Center), Agnes Kant (The Netherlands Pharmacovigilance Centre Lareb).	
15.00-15.30	*Coffee Break and networking*	
Session 8 15.30-17.00	Science and practice, joining forces in pharmacovigilance Chair: Francesco Salvo (*ISoP Board member*, *University of Bordeaux, France)*	
8.A 15.30-15.55	Science and practice, joining forces to moving pharmacovigilance forward: reflections from an epidemiological perspective	Toine Egberts *Utrecht University (Netherlands)*
8.B 15.55-16.20	Science and practice, joining forces to moving pharmacovigilance forward: reflections from a clinical perspective	Rob van Marum *Jeroen Bosch hospital Center of expertise Clinical Pharmacology (Netherlands)*
8.C 16.20-16.45	Science and practice, joining forces to moving pharmacovigilance forward: reflections from a pharmacovigilance perspective	Francois Montastruc *Faculty of Medicine and Toulouse University Hospital (France)*
16.45-17.00	Panel discussion with the participation of: Toine Egberts (Utrecht University*),* Rob van Marum (Jeroen Bosch hospital Center of expertise Clinical Pharmacology*),* Francois Montastruc (Faculty of Medicine and Toulouse University Hospital).	
	Closing remarks	
End of the Symposium		