2021 Symposium & Training for Eurasia

The societal importance of pharmacovigilance in Eurasia

Requirement for participation: ISoP membership			
Benefits provided by membership fee: • 12-month ISoP membership • Joining this Event • Joining other ISoP webinars • Accessing the *Drug Safety* journal		Membership LMICs	Event fee in addition to membership
	Academics, Regulators, and other Public Sectors LMICs	EUR.35	No
	Pharmaceutical industry, CROs, and other private sectors LMICs	EUR.75	EUR.200

Time zones										
	UTC+1	UTC+2	UTC+3	UTC+4	UTC+5	UTC+6	UTC+7	UTC+8	UTC+9	UTC+10
	UK DLS	CET DLS	Moscow	Azerbaijan Armenia	Uzbekistan	Kazakhstan	Indonesia	Singapore Mongolia	Korea	Vladivostok
Session A start	07:00	08:00	09:00	10:00	11:00	12:00	13:00	14:00	15:00	16:00
Session A end	08:30	09:30	10:30	11:30	12:30	13:30	14:30	15:30	16:30	17:30
30'										
Session B start	09:00	10:00	11:00	12:00	13:00	14:00	15:00	16:00	17:00	18:00
Session B end	10:30	11:30	12:30	13:30	14:30	15:30	16:30	17:30	18:03	19:30
30'										
Session C start	11:00	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00
Session C end	12:30	13:30	14:30	15:30	16:30	17:30	18:30	19:30	20:30	21:30
3x90'=270'=*4h30*										

	Event Day-1	Event Day-2	Event Day-3	Event Day-4
	Friday June 4	Saturday 5 June	Friday 18 June	Saturday 19 June
	Session 1A	Session 2A	Session 3A	Session 4A
	Session 1B	Session 2B	Session 3B	Session 4B
	Session 1C	Session 2C	Session 3C	Session 4C
18h	*4h30*	*4h30*	*4h30*	*4h30*

Event Day 1 Friday	***Committing HCPs and the Society to the Importance of Pharmacovigilance***	
Session	*Session Title*	*Timing*
Session 1A	***The societal importance of pharmacovigilance in Eurasia***	
1A.1	The societal importance of Pharmacovigilance and the role of ISoP (multiple panelists)	30'
1A.2	Overview of PV systems in Eurasia	30'
1A.3	The PV system in the Russian Federation: status and perspectives in COVID era	30'
		30'
Session 1B	***HCP's and Patients commitment to the safe use of medicines***	
1B.1	HCP's commitment to PV: Current issues and solutions	30'
1B.2	CIOMS WGXI: patient involvement in the development and safe use of medicines	30'
1B.3	Panel discussion interacting with Audience on the societal commitment to safe use of medicines	30'
		30'
Session 1C	***Improving the Safety Regulatory Framework in Eurasia***	
1C.1	The new EAEU GVP: Principles driving the revision and most significant changes	30'
1C.2	Regulatory strengthening, reliance and convergence to improve PV system effectiveness	30'
1C.3	Panel discussion interacting with Audience on the safety regulatory framework in Eurasia	30'
		4h30

Event Day 2 Saturday	***Medical Aspects of Pharmacovigilance***	
Session 2A	***Pharmacovigilance of vaccines***	
2A.1	Mechanisms of action of vaccines	15’
2A.2	Safety of anti-SARS-CoV-2 vaccines: Global experience	45’
2A.3	Panel discussion interacting with Audience on the safety of anti-SARS-CoV-2 vaccines	30’
		30’
Session 2B	***Medical pharmacovigilance***	
2B.1	ICSRs: definition, causality assessment, assessing case series	30’
2B.2	Pharmacovigilance of biosimilar products	30’
2B.3	Panel discussion interacting with Audience on the pharmacovigilance of biosimilars	30’
		30’
Session 2C	***Clinical pharmacovigilance***	
2C.1	Severe Cutaneous Adverse Reactions (SCARs)	30’
2C.2	Drug -Induced Liver Injury (DILI)	30’
2C.3	Panel discussion interacting with Audience on SCARs and DILI	30’
		4h30

Event Day 3 Friday	***Methods in Pharmacovigilance and Risk Minimisation***	
Session 3A	***Collecting and managing post-authorisation safety data***	
3A.1	Post-approval studies and other active safety data collection methods	30’
3A.2	*VigiBase, VigiFlow* and its ecosystem of tools for National PV Centres	30’
3A.3	Panel discussion interacting with Audience on post-authorisation data collection and management	30’
		30’
Session 3B	***Detection and management of safety signals***	
3B.1	Signal detection, signal management and re-evaluation of benefit vs risk of medicines	30’
3B.2	Using *VigiLyze* to search for signals in small data pools	30’
3B.3	Panel discussion interacting with Audience on signal detection and management	30’
		30’
Session 3C	***Risk minimisation and safety communications methods***	
3C.1	Risk minimisation methods	30’
3C.2	Overcoming pitfalls and challenges in safety communication	30’
3C.3	Panel discussion interacting with Audience on risk minimisation and safety communication	30’
		4h30

Event Day 4 Saturday	***Audits and Inspections***	
Session 4A	***Audits and Inspections: Rationale, Principles and legislations***	
4A.1	Principles of Quality System Management applied to pharmacovigilance	30’
4A.2	Legislations (EAEU/Russia) guiding the preparation and conduct of Audits and Inspections	30’
4A.3	Descriptions and analysis of the most common or critical inspection deficiencies (NRA)	30’
		30’
Session 4B	**Preparing, conducting and experiencing Audits and Inspections**	
4B.1	How NRAs expect MAH to prepare for inspections and behave when inspected (NRA)	30’
4B.2	Preparing MAH for Inspections and Audits (AIPM)	30’
4B.3	Panel discussion interacting with Audience on Audits and Inspections	30’
		30’
Session 4C	**Managing Corrective and Preventive Actions** (CAPA) **followed by Event wrap-up**	
4C.1	Managing Corrective Actions and Preventive Actions (CAPA)	30’
4C.2	Panel discussion interacting with Audience on Audits, Inspections and CAPA management	30’
4C.3	Meeting wrap-up (multiple panelists)	30’
		4h30