

ISoP Symposium & Training, Moscow September 23-24-25

Preliminary Agenda as of February 7th

Day 1 AM Wednesday 23 September Symposium		
08:30 - 09:00	30'	Registration.
09:00 - 09:30	30'	Introductory remarks
09:30 - 10:00	30'	Societal importance of pharmacovigilance in Russia Presentation
10:00 - 10:30	30'	Place of pharmacology in the Russian medical system
10:30 - 11:00	30'	Coffee break & Networking
11:00 - 11:30	30'	The pharmacovigilance system of the Russian Federation: Status and perspectives
11:30- 12:00	30'	HCP's commitment to pharmacovigilance-current issues and solutions
12:00- 12:30	30'	Severe Cutaneous Adverse Reactions (SCARs) update on pharmacovigilance and mechanistic knowledge
12:30 -13:25	55'	Lunch break and networking
13:25 - 13:30	5'	Introducing the session by session chair
13:30 - 14:00	30'	Postmarketing surveillance of biologics in the biosimilar era
14:00 - 14:30	30'	Update on CIOMS WG XI on patient involvement in the development and safe use of medicines
14:30 - 15:00	30'	Upcoming changes in the EAEU PV legislation
15:00 -15:30	30'	Tea break & Networking
15:30 -16:00	30'	License Holders' experience implementing the EAEU-GVP together with country-specific regulations
16:00 -17:00	60'	Panel discussion: Recommendations from regulatory, academic and industry stakeholder for the next version of the EAEU-GVP
17:00 -18:00	60'	First Russian ISoP EAEU Chapter assembly.
18:00		End of Day 1

Day 2 AM | Thursday 24 September | Symposium & Training

09:00 - 09:05	5'	<i>Introduction by session chair</i>
09:05 - 09:40	35'	Individual case safety reports: the fuel of pharmacovigilance activities
09:40 - 10:20	40'	Signal detection: principles and methods
10:20 - 10:50	30'	<i>Coffee break & Networking</i>
10:50 - 11:30	40'	Safety specifications and benefit vs risk evaluation: principles and methods
11:30 - 12:00	30'	Risk Management planning and Risk Minimisation. Principles and methods
12:00 - 13:00	60'	Practicum on Benefit vs risk evaluation and risk minimisation
13:00 - 14:00	60'	<i>Lunch break and networking</i>
14:00 - 14:05	5'	<i>Introduction by session chair</i>
14:05 - 14:30	25'	Early Postmarketing Phase Vigilance (EPPV) concept and practice in Japan
14:30 - 15:30	60'	Pharmacovigilance systems of EAEU countries beyond Russia <ul style="list-style-type: none"> ▪ Belarus (15') ▪ Kazakhstan (15') ▪ Armenia (15') ▪ Kyrgyzstan (15') (invited)
15:30 - 16:00	30'	<i>Tea break & Networking</i>
16:00 - 17:00	60'	PV systems in other Eurasian countries. This session will be involving the heads of the National Pharmacovigilance Centres of other Central Asian countries invited to join the meeting e.g. Azerbaijan, Uzbekistan, Georgia, Tajikistan and Mongolia.
17:00 - 18:00	60'	Improving the efficiency of PV systems by focusing efforts and resources on activities most value-adding for the safety of patients. Panel discussion involving the head of the National PV centres, Academics and MAH representatives.
18:00		<i>End of Day 2</i>

Day 3 AM Friday 25 September Training		
09:00 - 09:05	5'	Introduction by session chair
09:05 - 09:25	20'	The ICSR submission landscape: current status and perspectives
09:25 - 10:10	45'	The WHO-associated centre for international drug monitoring. Safety communication and systems made available to NRAs (VigiBase, VigiFlow, VigiLyse, VigiAccess etc...)
10:10 - 10:30	20'	Coffee break & Networking
10:30 - 11:00	30'	Applying advances technologies to pharmacovigilance. Report on the 2019 ISoP Boston meeting
11:00 - 11:30	30'	RZN's new E2B(R3) system
11:30 - 12:00	30'	MAH's experience of RZN's E2B(R3) database)
12:00 - 13:00	60'	ICSR management systems in Eurasian countries. Current status and needs. Panel discussion involving head of National PV Centres, UMC and ISoP panellists.
13:00 - 14:00	60'	Lunch break and networking

Day 3 PM Friday 25 September Workshop A on ICSR management systems		
<i>Workshop A intended for NRA personnel involved in ICSR management and/or signal detection chaired by Trainers from the WHO-associated centre for international drug monitoring.</i>		
14:00 - 14:05	5'	Introduction by session chair
14:05- 15:20	75'	Practicum: Performing signal detection using at the Country, Regional and Global level using the new functionalities of VigiLyze to access VigiBase.
15:20 - 15:50	30'	Tea break & Networking.
15:50 - 17:00	70'	Practicum Part 2: VigiLyze practicum continuing and VigiFlow demo upon request.
17:00		End of Workshop A on Day 3

Day 3 PM Friday 25 September Workshop B on Audits and Inspections		
<i>Workshop B intended for all other attendees chaired by Roszdravnadzor representative</i>		
14:00 - 14:05	5'	Introduction by session chair
14:05 - 14:30	25'	Principles of Quality System Management applied to pharmacovigilance
14:30 - 15:00	30'	How NRAs expect MAH to prepare organisation for inspections and behave when inspected

15:00 - 15:30	30'	Preparing MAH organisations for Inspections and Audits
15:30 - 16:00	30'	<i>Tea break & Networking.</i>
16:00 - 16:30	30'	Descriptions and analysis of the most common or critical deficiencies found during inspections
16:30- 17:00	30'	Managing Corrective Actions and Preventive Actions (CAPA) resulting from audits and inspections
17:00 -18:00	60	Panel discussion where presenters will be responding to the questions of the Audience on Audits, Inspection and CAPA management.
18:00		<i>End of Workshop B on Day 3</i>