



The International Society of Pharmacovigilance

Committed to Safer Use of Medicines Worldwide

2021 Symposium & Training for Eurasian Countries Симпозиум и тренинг ISoP для стран Евразии The societal importance of pharmacovigilance in Eurasia

Final Agenda

Friday June 4	<i>Committing HCPs and the Society to the Importance of Pharmacovigilance</i>
Session 1A	The societal importance of pharmacovigilance in Eurasia
Session 1B	HCP's and Patients commitment to the safe use of medicines
Session 1C	Improving the Safety Regulatory Framework in Eurasia

Saturday June 5	<i>Medical Aspects of Pharmacovigilance</i>
Session 2A	Pharmacovigilance of vaccines
Session 2B	Evaluating causality Pharmacovigilance of biological products
Session 2C	Clinical pharmacovigilance

Friday June 18	<i>Methods in Pharmacovigilance and Risk Minimisation</i>
Session 3A	Collecting and managing post-authorisation safety data
Session 3B	Detection and management of safety signals
Session 3C	Risk communications and risk minimisation methods

Saturday June 19	<i>Audits and Inspections</i>
Session 4A	Audits and Inspections: Rationale, Principles and legislations
Session 4B	Preparing, conducting and experiencing Audits and Inspections
Session 4C	Managing Corrective and Preventive Actions (CAPA) followed by Event wrap-up

Session schedule vs time zones										
	UTC+1	UTC+2	UTC+3	UTC+4	UTC+5	UTC+6	UTC+7	UTC+8	UTC+9	UTC+10
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

Day 1 - Friday 4 June		The societal importance of pharmacovigilance in Eurasia	
Session	Session Title	Speakers	Timing
Session 1A	Committing HCPs and the Society to the Importance of Pharmacovigilance <i>Chairpersons: Sergei Glagolev and Jean-Christophe Delumeau</i>		
1A.0	Introducing ISoP	○ Rebecca Chandler	5'
1A.1	<i>Panel discussion:</i> The societal importance of Pharmacovigilance and the role of ISoP.	○ Sergey Glagolev ○ Dmitry Sychev ○ Jean-Christophe Delumeau ○ Rebecca Chandler	25'
1A.2	Overview of PV system in the Eurasian Economic Union	○ Dmitriy Rozhdestvensky	30'
1A.3	The PV system in the Russian Federation: status and perspectives in COVID era	○ Kirill Gorelov	30'
		Intermission	30'
Session 1B	HCP's and Patients commitment to the safe use of medicines <i>Chairpersons: Dmitry Sychev and Naira Romanova</i>		
1B.1	HCP's commitment to PV: Current issues and solutions	○ Kirill Gorelov ○ Alexandr Matveev	30'
1B.2	CIOMS XI: Patient involvement in the development and safe use of medicines	○ Manal Younus	30'
1B.3	<i>Panel discussion:</i> The societal commitment to safe use of medicines.	○ Dmitry Sychev ○ Naira Romanova ○ Manal Younus ○ Sergey Glagolev ○ Kirill Gorelov ○ Alexandr Matveev	30'
		Intermission	30'
Session 1C	Improving the Safety Regulatory Framework in Eurasia <i>Chairpersons: Alla Kuchko and Manal Younus</i>		
1C.1	The new EAEU GVP: Principles driving the revision and most significant changes	○ Svetlana Setkina	30'
1C.2	Regulatory strengthening, reliance and convergence to improve PV systems	○ Jean-Christophe Delumeau	30'
1C.3	<i>Panel discussion:</i> The safety regulatory framework in Eurasia: Panel discussion introduced by Jean-Christophe Delumeau. <i>May be expanded up to 60 minutes.</i>	<i>Involving the Chairpersons, the presenters and all regulators from the Eurasian Region interested participating.</i>	30'+
End of June 4 Conference			

Day 2 - Saturday 5 June		Medical aspects of pharmacovigilance	
Session	Session Title		Timing
Session 2A	Pharmacovigilance of vaccines <i>Chairpersons: Alexandr Matveev and Rebecca Chandler</i>		
2A.1	Overview of the mechanisms of action of vaccines	○ <i>Dmitriy Gorenkov</i>	15'
2A.2	The safety of anti-SARS-CoV-2 vaccines: Global experience	○ <i>Inna Dolzhikova</i> ○ <i>Saad Shakir</i>	45'
2A.3	<i>Panel discussion:</i> The safety of anti-SARS-CoV-2 vaccines.	○ <i>Alexandr Matveev</i> ○ <i>Rebecca Chandler</i> ○ <i>Dmitriy Gorenkov</i> ○ <i>Inna Dolzhikova</i> ○ <i>Saad Shakir</i> ○ <i>Gianluca Trifirò</i>	30'
		Intermission	30'
Session 2B	Evaluating causality Pharmacovigilance of biological therapeutic products <i>Chairpersons: Irina Poddubnaya and Manal Younus</i>		
2B.1	ICSRs: definition, causality assessment, assessing case series	○ <i>Ruth Savage</i>	30'
2B.2	Pharmacovigilance of biological products	○ <i>Gianluca Trifirò</i>	30'
2B.3	<i>Panel discussion:</i> Pharmacovigilance of biosimilars and other biological products.	○ <i>Irina Poddubnaya</i> ○ <i>Manal Younus</i> ○ <i>Gianluca Trifirò</i> ○ <i>Alexandr Matveev</i> ○ <i>Saad Shakir</i>	30'
		Intermission	30'
Session 2C	Clinical pharmacovigilance <i>Chairpersons: Dmitriy Sychev and Jan Petráček</i>		
2C.1	Drug -Induced Liver Injury (DILI)	○ <i>Alexandr Matveev</i>	30'
2C.2	Severe Cutaneous Adverse Reactions (SCARs)	○ <i>Maja Mockenhaupt</i>	30'
2C.3	<i>Panel discussion:</i> Drug -Induced Liver Injury and Severe Cutaneous Adverse Reactions.	○ <i>Dmitriy Sychev</i> ○ <i>Jan Petráček</i> ○ <i>Alexandr Matveev</i> ○ <i>Maja Mockenhaupt</i>	30'
<i>End of June 5 Conference</i>			

Day 3 - Friday 18 June		Methods in Pharmacovigilance and Risk Minimisation	
<i>Session</i>	<i>Session Title</i>		<i>Timing</i>
Session 3A	Collecting and managing post-authorisation safety data <i>Chairpersons: Svetlana Sekina and Jan Petráček</i>		
3A.1	Post-approval studies and other active safety data collection methods	○ Vitaliy Polivanov	30'
3A.2	VigiBase, VigiFlow and its ecosystem of tools for National PV Centres	○ Helena Sköld	30'
3A.3	<i>Panel discussion:</i> Post-authorisation data collection and management.	○ Svetlana Sekina ○ Jan Petráček ○ Kirill Gorelov ○ Ruth Savage ○ Vitaliy Polivanov ○ Helena Sköld	30'
Intermission			30'
Session 3B	Detection and management of safety signals <i>Chairpersons: Vitaliy Polivanov and Yue Qun-Ying</i>		
3B.1	Signal detection and management and re-evaluation of the benefit vs risk	○ Jan Petráček	30'
3B.2	Using VigiLyze to search for signals in small data pools	○ Rebecca Chandler	30'
2B.3	<i>Panel discussion:</i> Signal detection and signal management.	○ Vitaliy Polivanov ○ Yue Qun-Ying ○ Jan Petráček ○ Rebecca Chandler	30'
Intermission			30'
Session 3C	Risk communications and risk minimisation methods <i>Chairpersons: Vitaliy Polivanov and Rebecca Chandler</i>		
3C.1	Risk communications and risk minimisation methods	Jan Petráček	30'
3C.2	Overcoming pitfalls and challenges in safety communication	Dmitry Sychev	30'
3C.3	<i>Panel discussion:</i> Risk communications and risk minimisation methods.	○ Vitaliy Polivanov ○ Rebecca Chandler ○ Jan Petráček ○ Dmitriy Sychev ○ Naira Romanova ○ Alla Kuchko ○ Malik Abdrakhmanov ○ Zhyldyz Zhumagulova	30'
<i>End of June 18 Conference</i>			

Day 4 - Saturday 19 June		Audits and Inspections	
Session	Session Title		Timing
Session 4A	Audits and Inspections: Rationale, Principles and legislations <i>Chairpersons: Kirill Gorelov and Olga Ermishina</i>		
4A.1	Principles of Quality System Management applied to pharmacovigilance	○ <i>Mandeep Rai</i>	30'
4A.2	EAEU Regulation guiding preparation and conduct of Audits and Inspections	○ <i>Anatoliy Krasheninnikov</i>	30'
4A.3	Descriptions and analysis of most common/important inspection deficiencies	○ <i>Mandeep Rai</i>	30'
		Intermission	30'
Session 4B	Preparing, conducting and experiencing Audits and Inspections <i>Chairpersons: Almira Galeeva and Deirdre McCarthy</i>		
4B.1	How HA expect MAHs to prepare for inspections and behave when inspected	○ <i>Malik Abdrakhmanov</i>	30'
4B.2	Preparing License Holders' organisations for Audits and Inspections	○ <i>Olga Ermishina</i>	30'
4B.3	<i>Panel discussion:</i> Preparing, conducting and experiencing Audits and Inspections.	○ <i>Almira Galeeva</i> ○ <i>Deirdre McCarthy</i> ○ <i>Mandeep Rai</i> ○ <i>Anatoliy Krasheninnikov</i> ○ <i>Malik Abdrakhmanov</i> ○ <i>Olga Ermishina</i> ○ <i>Kirill Gorelov</i>	30'
		Intermission	30'
Session 4C	Managing Corrective and Preventive Actions <i>Chairpersons: Svetlana Sekina and Naira Romanova</i>		
4C.1	Managing Corrective Actions and Preventive Actions (CAPAS)	○ <i>Lola Khodzhayova</i>	30'
4C.2	<i>Panel discussion:</i> CAPA management.	○ <i>Svetlana Setkina</i> ○ <i>Naira Romanova</i> ○ <i>Mandeep Rai</i> ○ <i>Olga Ermishina</i> ○ <i>Lola Khodzhayova</i> ○ <i>Kirill Gorelov</i> ○ <i>Malik Abdrakhmanov</i> ○ <i>Alla Kuchko</i>	30'
4C.3	<i>Panel discussion.</i> <i>Meeting wrap-up and concluding remarks on the whole Event. Chaired by Sergei Glagolev and J-C. Delumeau</i>	○ <i>Sergey Glagolev</i> ○ <i>Jean-Christophe Delumeau</i> ○ <i>Dmitry Sychev</i> ○ <i>Rebecca Chandler</i>	30'
<i>End of June 19 Conference and end of the event</i>			