



# 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 and Information to Connect

<b>Friday June 4</b>	<b><i>Committing HCPs and the Society to the Importance of Pharmacovigilance</i></b>
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

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

<b>Friday June 18</b>	<b><i>Methods in Pharmacovigilance and Risk Minimisation</i></b>
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

<b>Saturday June 19</b>	<b><i>Audits and Inspections</i></b>
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

Teleconference System	ISoP Zoom Platform	
Link to connect to the Event as Audience	<a href="https://us02web.zoom.us/j/85882111433?pwd=TnUyYmVtSFY2U1V1c1B4amEzeWxmUT09">https://us02web.zoom.us/j/85882111433?pwd=TnUyYmVtSFY2U1V1c1B4amEzeWxmUT09</a>	
<p>While connected as <i>Audience</i> with the above URL please use the Q&amp;A functionality to ask question in writing or to request speaking. При подключении в качестве <i>аудитории</i> к сеансам с указанным выше URL-адресом используйте функцию вопросов и ответов, чтобы задать вопрос в письменной форме или запросить выступление.</p> <p>If you are expected to connect as <i>presenter or panelist</i>, please use the URL Link to connect as "Panelist" included into the latest message you received from <i>Angelica Heliconia</i>. Если ожидается, что вы подключитесь в качестве докладчика или участника дискуссии, используйте URL-ссылку для подключения в качестве «участника дискуссии», включенную в последнее сообщение, которое вы получили от <i>Angelica Heliconia</i>.</p>		
Meeting ID (if requested):	858 8211 1433	Passcode (if requested): 11541219
Any question:	<a href="mailto:Jean-christophe.delumeau@outlook.com">Jean-christophe.delumeau@outlook.com</a>	<a href="mailto:Administration@isoponline.org">Administration@isoponline.org</a>
Support via WhatsApp:	Christopher (ISoP): +65 9627 6948	Sophie (ISoP): +44 777 306 2841
Поддержка на русском:	Anastasia (RZN) +7 926 387 0126	Elena (RMAPO) +7 914 899 3453
To become an ISoP member:	<a href="http://www.isoponline.org">www.isoponline.org</a>	<a href="mailto:Administration@isoponline.org">Administration@isoponline.org</a>

Day 1 - Friday 4 June		The societal importance of pharmacovigilance in Eurasia	
Session	Session Title	Speakers	Timing
<b>Session 1A</b>	<b>Committing HCPs and the Society to the Importance of Pharmacovigilance</b> <i>Chairpersons: Sergei Glagolev and Jean-Christophe Delumeau</i>		
1A.0	Introducing ISoP	○ <a href="#">Rebecca Chandler</a>	5'
1A.1	<i>Panel discussion:</i> The societal importance of Pharmacovigilance and the role of ISoP.	○ <a href="#">Sergey Glagolev</a> ○ <a href="#">Jean-Christophe Delumeau</a> ○ <a href="#">Rebecca Chandler</a> ○ <a href="#">Dmitry Sychev</a> ○ <a href="#">Vladimir Petrov</a>	25'
1A.2	Overview of PV system in the Eurasian Economic Union	○ <a href="#">Dmitriy Rozhdestvensky</a>	30'
1A.3	The PV system in the Russian Federation: status and perspectives in COVID era	○ <a href="#">Kirill Gorelov</a>	30'
		Intermission	30'
<b>Session 1B</b>	<b>HCP's and Patients commitment to the safe use of medicines</b> <i>Chairpersons: Dmitry Sychev and Naira Romanova</i>		
1B.1	HCP's commitment to PV: Current issues and solutions	○ <a href="#">Kirill Gorelov</a> ○ <a href="#">Alexandr Matveev</a>	30'
1B.2	CIOMS XI: Patient involvement in the development and safe use of medicines	○ <a href="#">Manal Younus</a>	30'
1B.3	<i>Panel discussion:</i> The societal commitment to safe use of medicines.	○ <a href="#">Dmitry Sychev</a> ○ <a href="#">Naira Romanova</a> ○ <a href="#">Manal Younus</a> ○ <a href="#">Sergey Glagolev</a> ○ <a href="#">Kirill Gorelov</a> ○ <a href="#">Alexandr Matveev</a>	30'
		Intermission	30'
<b>Session 1C</b>	<b>Improving the Safety Regulatory Framework in Eurasia</b> <i>Chairpersons: Alla Kuchko and Manal Younus</i>		
1C.1	The new EAEU GVP: Principles driving the revision and most significant changes	○ <a href="#">Svetlana Setkina</a>	30'
1C.2	Regulatory strengthening, reliance and convergence to improve PV systems	○ <a href="#">Jean-Christophe Delumeau</a>	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
<b>Session 2A</b>	<b>Pharmacovigilance of vaccines</b> <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'
<b>Session 2B</b>	<b>Evaluating causality   Pharmacovigilance of biological therapeutic products</b> <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'
<b>Session 2C</b>	<b>Clinical pharmacovigilance</b> <i>Chairpersons: Dmitriy Sychev and Jan Petrůček</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 Petrůček</i> ○ <i>Alexandr Matveev</i> ○ <i>Maja Mockenhaupt</i>	30'
<i>End of June 5 Conference</i>			

<b>Day 3 - Friday 18 June</b>		<b>Methods in Pharmacovigilance and Risk Minimisation</b>	
<i>Session</i>	<i>Session Title</i>		<i>Timing</i>
<b>Session 3A</b>	<b>Collecting and managing post-authorisation safety data</b> <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'
<i>Intermission</i>			30'
<b>Session 3B</b>	<b>Detection and management of safety signals</b> <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'
<i>Intermission</i>			30'
<b>Session 3C</b>	<b>Risk communications and risk minimisation methods</b> <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 Abdrakhamnov ○ Zhyldyz Zhumagulova	30'
<i>End of June 18 Conference</i>			

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