

ALIMS Simpozijum 2.0

ALIMS Symposium 2.0



**Program
za klinička ispitivanja
i veterinarske lekove**

**Program
of clinical trials
and veterinary drugs**

24 – 26. 10. 2024.

Kopaonik, Srbija

01

24.10.2024.

Sala Izvor
Hall Izvor

17:00–18:00 **Koktel dobrodošlice**
Welcome cocktail

18:00–20:00 Obeležavanje 20 godina rada ALIMS:
Svečano otvaranje simpozijuma, pozdravni govor zvaničnika,
interaktivna panel diskusija direktora
i rukovodilaca regulatornih tela iz Evrope
Celebrating 20 years of ALIMS:
Formal opening of the symposium, official welcome speech,
interactive panel discussion with directors
and managers of regulatory bodies from Europe

Moderator / Moderator:

Jelena Mitrašinić, ALIMS

Saša Jaćović, direktor ALIMS / **ALIMS director**

Emer Cooke, direktor EMA / **EMA director**

Petra Doerr, direktor EDQM / **EDQM director**

Maja Vučković Krčmar, Kancelarija EU delegacije u RS
Delegation of the European Union (EU)
to the Republic of Serbia

Fabio Scano, direktor Kancelarije SZO u RS
director of WHO office in Republic of Serbia

Mirjana Vučićević, Privredna komora Srbije
Serbian Chamber of Commerce

Bojan Trkulja, direktor INOVIA / **INOVIA director**

Ana Popović, direktor GENEZIS / **GENEYIS director**

Predstavnik Ministarstva zdravlja Srbije
Representative of the Ministry of Health of Serbia

Uvodno predavanje
Introductory lecture

Saša Jaćović, direktor ALIMS / **ALIMS director**

Panel visokih predstavnika
Panel of High Representatives

Moderator / Moderator:

Pavle Zelić, ALIMS

Panelisti / Panelists:

Saša Jaćović, direktor ALIMS / **ALIMS director**

Nataša Grubiša, direktor ALMBIH / **ALMBIH director**

Snežana Mugoša, direktor CinMED / **CinMED director**

Sefedin Jonuzi, direktor MALMED / **MALMED director**

Cecilia Müller, direktor NNGYK / **NNGYK director**

Bogdan Kirilov, direktor BDA / **BDA director**

Dragoş Guţu, direktor AMDM / **AMDM director**

Blerina Kaza, direktor AKBPM / **AKBPM Director**

20:00–22:00 Večera u restoranu hotela Gorski
Dinner at hotel Gorski



9:30–11:00	Veterinarski lekovi: U susret novim izazovima Sesija 1: Klinička ispitivanja veterinarskih lekova Veterinary medicines: Meeting new challenges Session 1: Clinical trials of veterinary medicines	Moderator / Moderator: Zorana Radonjić, ALIMS
	Procena za odobrenje veterinarskog kliničkog ispitivanja Assessment for Authorisation of a Veterinary Clinical Trial	Sophie Barreateau , ANSES Francuska (online predavač) ANSES France (online speaker)
	Klinička ispitivanja: Gde smo i kuda idemo? Clinical Trials: Where are we and where are we headed?	Jelena Anđelković, ALIMS
	Studije neinferiornosti: Koliko loše je još uvek dobro? Non-inferiority studies: How bad is still good enough?	Ivan Soldatović , Medicinski fakultet Univerziteta u Beogradu University of Belgrade - Faculty of Medicine
11:00–11:30	Kafe pauza / Coffee break	
11:30–13:00	Veterinarski lekovi: U susret novim izazovima Sesija 2: Novine u regulativi Veterinary medicines: Meeting new challenges Session 2: News in regulation	Moderator / Moderator: Zorana Radonjić, ALIMS
	RIMS i veterinarski lek RIMS and veterinary drug	Milan Đokić, ALIMS Jelena Anđelković, ALIMS
	Veterinarski lekovi za oralnu primenu - nove smernice Veterinary drugs for oral use - new guidelines	Stefan Đurić, ALIMS
	Varijacije EU/RS: (Ne)Usklađenost Variations EU/RS:	Jelena Stevanović-Gročić, ALIMS
	CEP 2.0 Šta nam donosi? CEP 2.0 What does it bring us?	Aleksandra Labudović, ALIMS
13:00–15:00	Pauza za ručak / Lunch break	





15:00–16:30	Procena i odobravanje kliničkih ispitivanja lekova i medicinskih sredstava: zahtevi, proces i novine Assessment and approval of clinical trials of medicines and medical devices: requirements, processes and news	Moderator / Moderator: Biljana Andrić, ALIMs
	Put od submisije do odobrenja - regulatorni zahtevi, praktični aspekti i dosadašnja iskustva Path from submission to approval - regulatory demands, practical aspects and experiences	Biljana Latinović, ALIMs
	Ključni aspekti procene dokumentacije o kvalitetu ispitivanog leka (IMPD) Key aspects in the evaluation of documentation on the quality of tried drug (IMPD)	Katarina Todorović, ALIMs
	Primena veštačke inteligencije u kliničkim ispitivanjima: izazovi i mogućnosti Application of artificial intelligence in clinical trials: Challenges and opportunities	Aleksandra Bjelovuk, ALIMs
		Dubravka Mišković, ALIMs
	Pregled regulatornih zahteva i aktivnosti ALIMs-a iz oblasti kliničkih ispitivanja medicinskih sredstava Overview of regulatory requirements and activities of ALIMs in the field of clinical trials of medical devices	Sonja Selić, ALIMs

16:30–17:00 Kafe pauza / **Coffee break**



02

25.10.2024.



Sala Pogled
Hall Pogled

17:00–18:30 ICH E6(R3): Uspon profila decentralizovanih kliničkih ispitivanja (DCT) i odgovornosti – u susret izazovima
ICH E6(R3): The rising profile of decentralized clinical trials (DCT) and responsibilities - to meet the challenges

Moderator / Moderator:

Violeta Ristić, ALIMIS

Panelisti / Panelists:

Siniša Radulović, Medicinski fakultet u Beogradu
University of Belgrade - Faculty of Medicine

Ivana Tadić, PSI

Iva Prunić, IQVIA

18:30–21:00 Večera u restoranu hotela Gorski
Dinner at hotel Gorski

21:00 Koktel - restoran Nacionalna klasa
Cocktail - Restaurant "Nacionalna Klasa"

Organizator



Agencija za lekove
i medicinska sredstva Srbije

Koorganizatori



PRIVREDNA
KOMORA
SRBIJE

1857



INOVIA

Udruženje proizvođača inovativnih
lekova



Pokrovitelj



Република Србија
МИНИСТАРСТВО ЗДРАВЉА

