



Regional
Conference
on Rare Diseases
2022

Clinical trials in rare diseases:
The path of therapy from trial to a patient

25.10.2022. , Novi Sad

MASTER CENTAR NOVOSADSKOG SAJMA, HAJDUK VELJKOVA BR. 11, HIBRIDNA KONFERENCIJA

09:00 – 10:00 **Registration of participants, welcome coffee**

10:00 – 10:30 Welcome introductory greetings:

- **First Lady of the Republic of Serbia, Tamara Vučić**
- **Ministry of Health Serbia, TBC**
- **National Health Insurance Fund Serbia, TBC**
- **Kal research Initiative - R69 Initiative, Helen Hernandez**
- **Bojana Mirosavljević, -association "Life", Rare Diseases Database for Balkan**

Rare diseases and clinical trials for rare diseases - perspective of EU regulatory bodies and EURORDIS

10:45 – 11:00 · **European Organization for Rare Diseases (EURORDIS), Francois Houyez**

Availability of clinical trials, opportunities and challenges

11:10 – 11:15 · **European Medicines Agency (EMA), CHMP Committee for Medicinal Products and Human Use, Margareta Bego**

The role of European Medicines Agency (EMA) and EU national competent authorities in authorization of medicines for rare diseases

11:15-11:30 · **European Medicines Agency (EMA), Paediatric Committee, Tomasz Grybek**

The role of Paediatric Committee PDCO EMA

Clinical trials in rare diseases and good clinical practice, the role of national medicines agencies - examples from the region

11:30 – 11:50 · **Medicines and Medical Devices Agency of Serbia (ALIMS) Jadranka Mirković**

11:50 – 12:10 · **Ethics Committee of Serbia, Goran Vasović**

12:10 – 12:30 · **Agency for Medicines and Medical Devices, Bosnia and Herzegovina (ALMBiH) Tatjana Ponorac**

12:30 – 12:50 · **Medicines and Medical Devices Agency of Montenegro (CinMED) Maja Lisičić**

12:50 – 13:10 · **Medicines and Medical Devices Agency of North Macedonia (MALMED) Marija Trajčuleski**

13:15 – 14:15 **Lunch**

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Panel discussion: Clinical trials for rare diseases "Opportunities and challenges"

14:30 – 15:30

Panelists:

Dorica Dan, EURORDIS
Dr Vesna Branković, IQVIA
Tomasz Grybek, EMA
Bojan Trkulja, INOVIA
Maja Stojiljković, IMGGI
Zoran Aćimović, CRA Academy

Q&A

Panel discussion: Clinical trials - how accessible they are to patients living with rare diseases

16:00 – 17:00

Panelists:

Dr Dimitrije Nikolić, University Children Hospital Tirsova, Belgrade
Dr Galina Stevanović, Clinic for Neurology and Psychiatry for Children and Youth, Belgrade
Jadranka Mirković, ALIMIS (TBC)
Ivana Golubović, HAE patient
Vivian Fernandez, RegenxBio
Anđelka Stupar, patient advocate (TBC)
Olivera Jovović, (The National Organization for Rare Diseases of Serbia)

17:00 – 17:30

Conclusions, closing procedure



PROJEKAT PODRŽALI:



PROJEKAT POMOGLI:



PROJEKAT POKRENUT
OD STRANE UDRUŽENJA

