



## **Advanced GCP course**

**20 February 2023**

10:00 – 10:15 - Opening remarks

10:15 - 11:00 - History and Principles of ICH-GCP/ Istorija i principi dobre kliničke prakse

11:00 - 11:50 - Drug safety and pharmacovigilance/ Farmakovigilanca

11:50 - 12:05 - Coffee break/ pauza za kafu

12:05 - 12:55 - Pediatric clinical trials/ Pedijatrijska klinička ispitivanja

12:55 - 13:40 - Ethical decision-making/ vežba donošenje etičkih odluka

13:40 - 14:00 - Lunch break/ pauza za ručak

14:00 - 14:50 - Informed Consent process/ Proces dobijanja saglasnosti informisanog ispitanika

14:50 - 15:35 - Orphan drugs (drugs for the rare diseases)/ Lekovi za retke bolesti

15:35 - 16:20 - Helsinki Declaration and other documents on ethics/ Helsinška Deklaracija i druga dokumenta o etici

16:20 - 17:05 - Patient Centric Trials / Klinička ispitivanja usmerena na ispitanika

17:05 - 17:50 - Bioequivalence studies / bioavailability / biosimilars/ Studije biološke raspoloživosti i biološke ekvivalentnosti

17:50 – 18:20 - Exit test