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FARMAKOMETRIJSKI MODELI – SAVREMEN ALAT ZA KVANTIFIKACIJU VARIJABILNOSTI I INDIVIDUALIZACIJU REŽIMA DOZIRANJA LEKOVA

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Farmakometrijski modeli predstavljaju moćni alat i neizostavni su aspekt u savremenim farmaceutskim istraživanjima i kliničkoj praksi. Oni obezbeđuju kvantitativni okvir za razumevanje složene interakcije između karakteristika leka, pacijenta i bolesti, omogućavajući izbor leka i režima doziranja radi optimizacije terapijskih ishoda (1). Pacijenti se međusobno razlikuju u odgovoru na lekove zbog genetskih, fizioloških, kliničkih ili faktora sredine. Različit odgovor na terapiju može biti farmakokinetičke, farmakodinamičke ili prirode same bolesti, što ukazuje da jedna doza ne odgovara svim pacijentima. U cilju stratifikacije režima doziranja za specifične populacije pacijenata, rešavanje varijabilnosti je od suštinskog značaja. Jedna od ključnih prednosti farmakometrijskih modela leži u njihovoj sposobnosti da razdvoje različite nivoe varijabilnosti u ponašanju leka, a posebno u kvantifikaciji i matematičkom opisivanju izvora interindividualne varijabilnosti, kao i predviđanju kako će različiti pacijenti reagovati na lek. Upravo su ova znanja od neprocenjive vrednosti za specifične populacije pacijenata kako bi se identifikovali optimalni režimi doziranja koji obezbeđuju maksimalnu efikasnost uz minimalne neželjene efekte terapije. Farmakometrijskim-modelima vođeno doziranje je značajno kod pedijatrijskih, starijih, kritično-obolelih ili pacijenata sa oslabljenom funkcijom jetre/bubrega, gde preporuka o jedinstvenom režimu doziranja za sve pacijente često nije primenljiva u kliničkoj praksi (2). U okviru predavanja će biti prikazani rezultati istraživanja gde farmakometrijski modeli doprinose novim saznanjima i unapređuju razvoj lekova otključavanjem potencijala personalizovane medicine.

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PHARMACOMETRIC MODELS - A MODERN TOOL FOR QUANTIFYING VARIABILITY AND INDIVIDUALIZING DRUG DOSING REGIMENS

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Pharmacometric models are a powerful tool and an essential aspect of modern pharmaceutical research, drug development and clinical practice. They provide a quantitative framework for understanding the complex interaction between drug characteristics, patients, and diseases, enabling the selection of drugs and dosing regimens to optimize therapeutic outcomes (1). Patients vary in their response to medications due to genetic, physiological, clinical, or environmental factors. Different responses to therapy can be of pharmacokinetic, pharmacodynamic, or disease-related nature, indicating that one dose does not fit all patients. Addressing the variability is essential for stratifying dosing regimens for specific patient populations. One of the key advantages of pharmacometric models lies in their ability to distinguish different levels of variability in drug behavior, especially in quantifying and mathematically describing the sources of interindividual variability, as well as predicting how different patients will react to the drug. This knowledge is invaluable for specific patient populations to identify optimal dosing regimens that provide maximum efficacy with minimal side effects. Model-informed dosing is significant in pediatrics, elderly, critically ill patients, or patients with impaired liver/kidney function, where a one-size-fits-all dosing recommendation is often not applicable (2). The lecture will present research results where pharmacometric models contribute to new insights and improve drug development by unlocking the potential of personalized medicine.

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