Special Lectures by Dr. Michael Weiss

I. Introduction to Pharmacometrics

Aim:

The course will give an introduction to pharmacometrics specifically population pharmacokinetics (popPK). The application in experimental and clinical pharmacology is discussed and practical issues with modeling are explored theoretically and with computer exercises (ADAPT5).

1. **Terminology and Definitions**
2. **Objective of Population PK**
3. **Methods**
   Naive pooled data approach, Standard two-stage approach, One-stage analysis (popPK)
4. **Bayesian estimation**
5. **Advantages and Disadvantages**
   Sparse sampling situation, Model misspecification
6. **Mixed-effects concept**
   Fixed effects, Between subject variability, Residual variability
7. **Patient covariates**
   Explain between subject variability
8. **Maximum likelihood approach**
   Log-likelihood ratio, AIC, Quality of fit
9. **Simulation**
   Deterministic simulation, Stochastic simulation (Monte Carlo simulation)
10. **Computer exercises using ADAPT5**

II. Principles and planning of clinical pharmacokinetic studies

1. **Model selection**
2. **Study design**
3. **Sampling design**
4. **Therapeutic drug monitoring**
5. **Drug dissolution and absorption**
6. **In vitro-in vivo correlation**