Webinar

FROM PBPK TO PBFTPK (PHYSIOLOGICALLY BASED FINITE TIME PHARMACOKINETIC) MODELS

Wednesday, 1st September 2021, 15:00 pm (CET)

ATHENA Research Centre organizes a half-day webinar covering novel concepts in PBPK and PBFTPK modelling.

Webinar summary

This half-day webinar is intended for academics/students or scientists working in Academia, pharmaceutical industries, regulatory agencies, and contract research organizations.

The webinar will begin with a talk on the food effect mechanisms and incorporation in PBPK models. Case studies of application of PBPK models for food effect predictions in industry and regulatory applications will be presented. The gaps and opportunities will be underlined.

The next talk will focus on PBPK modeling approaches to inform virtual bioequivalence trials. The concept of in vitro in vivo extrapolation (IVIVE) in biopharmaceutics as well as the role of inter-occasion variability in virtual bioequivalence assessments will be discussed.

The third talk will describe the fundamental aspects of PBFTPK models. The models were build on two principles i) drugs are absorbed passively for a finite period of time, τ and ii) time absorption constrains linked with the gastrointestinal transit times of drug in the stomach, the small intestines and the colon were applied. Zero- or first-order input is used for the $(PBFTPK)_0$ and $(PBFTPK)_1$ models, respectively. Simulations based on various scenarios for model parameters and single or multiple input rates will be presented.

The fourth talk will focus on the PBFTPK software. Several case studies for data set analyses using the PBFTPK software will be presented. Data will represent the time evolution of drug concentration in the blood stream after oral administration of formulations. A step-by-step approach for each case will guide researchers in choosing the most appropriate model and determining the optimum and realistic parameters. Physiological constraints will be considered in guiding the selection of model parameters. The audience is invited to provide their data for an on-stage analysis.

The final talk will provide an overview of the impact of PBFTPK models on the scientific and regulatory aspects of biopharmaceutical sciences. The meaning of the extent and rate of absorption parameters will be questioned while the estimation of absolute bioavailability from oral data exclusively will be presented. The finite time of absorption concept will be used for the development of an holistic biopharmaceutic-pharmacokinetic classification system to facilitate drug discovery and development.

Programme

TIME (CET)	SPEAKER	TOPIC
14:55	Panos Macheras Department of Pharmacy, National and Kapodistrian University of Athens / PharmaInformatics Unit, Research Center ATHENA, Athens, Greece	Welcome; introduction
15:00	<u>Filippos Kesisoglou</u> Merck & Co., Inc., Rahway, NJ, USA	Can PBPK Modeling Streamline Food Effect Assessments?
15:45	Ioannis Loisios Konstantinidis Novartis, Basel, Switzerland	PBPK-IVIVE linked models to inform virtual bioequivalence trials
16:30	Panos Macheras Department of Pharmacy, National and Kapodistrian University of Athens / PharmaInformatics Unit, Research Center ATHENA, Athens, Greece	The rise of PBFTPK models
17:15-17:30	Break	
17:30	AthanasiosTsekouras Department of Chemistry, National and Kapodistrian University of Athens / PharmaInformatics Unit, Research Center ATHENA, Athens, Greece	Analysis of C, t data using the "PBFTPK" software
18:15	Panos Macheras Department of Pharmacy, National and Kapodistrian University of Athens / PharmaInformatics Unit, Research Center ATHENA, Athens, Greece	The impact of PBFTPK models: From the first Lewis Sheiner digoxin bioavailability paper to the estimation of absolute bioavailability from oral data exclusively to drug discovery and development
19:00-19:30	Discussion	

Registration-Fees

- Industry, CROs: 300 €
- Academia-Government: 200 €
- Student : 50 €