EAFP Annual Conference 2019: Krakow, Poland - Preconference (15th of May 2019)

Virtual clinical trials and virtual twin approach for drug pharmacokinetics and cardiac safety assessment

The aim of the seminar is to present and discuss drugs cardiac safety assessment with a focus on the clinical trials and post-approval stages. The current safety testing paradigm based on the clinical trials will be compared against the *in silico* centred approach. Additional aim includes introduction and discussion of the recently introduced virtual twin concept.

The planned seminar will be a combination of lectures and exercises based on real-life clinical examples.

Schedule and short description of activities

9:00 Welcome and workshop overview – dr. Sebastian Polak

9:15 Introductory lecture – dr. Sebastian Polak

General introduction to the virtual clinical trials and virtual twin concepts in the field of pharmacy and medicine. Focus will be put on the *in silico* realized computational methods utilized currently for the clinical trials simulations, pharmaceutical education, drug formulation design, individualization of the pharmacotherapy.

9:45 Lecture – dr. Sebastian Polak

Description of the virtual heart cell – basic concepts and biophysical background. I*n silico* implementation of the computational model of single cell and 1D model of the human ventricle – parametrization, output and its interpretation.

10:15 Case study – dr. Zofia Tylutki

The case study will be presented in the form of an interactive presentation, and the discussed examples will describe the analysis of the virtual cardiac cell simulation results. The surrogates of cardiac arrhythmias will be discussed. The influence of individual patient characteristics, such as the ions plasma concentrations or heart rate, on the drug effect on human cardiac electrophysiology will be identified during the case study discussion.

11:00 Case study – dr. Zofia Tylutki

The case study will be presented in the form of an interactive presentation, and the discussed examples will describe the problem of drug therapy individualization and optimization. The cases of a healthy Caucasian population, mutant in genes responsible for metabolic enzymes, and the special populations will be shown. PBPK and QSP models combination for maximizing the efficacy and safety of individual patient will be discussed with clinical examples. During the lecture, the sophisticated software used in the industry to support decision-making in drug development will be used.