Application of modeling and simulation to accelerate drug development for parasitic tropical diseases-opportunities and challenges

Co-Chairs
Yaning Wang, PhD and Sherwin K. B. Sy, PhD

Description
New antiparasitic drugs are urgently needed to prevent and treat tropical diseases such as malaria and Chagas disease, which affect millions of people living under economically challenging conditions each year (1). In the past few years, new funds for tropical diseases have given new impetus to antiparasitic drug discovery and development. One of the critical challenges for antiparasitic drug development is to develop effective and clinically feasible dosage regimens to increase the success rate of clinical trials while mitigating dose-related adverse event occurrences.

Pharmacokinetic/pharmacodynamic (PK/PD) modeling and simulation have proven to be an indispensable method to inform optimal dose by quantitatively characterizing the relationship between exposure and treatment outcomes. Since parasites are the direct target of antiparasitic treatment, in vitro and animal data with a wide range of dose regimens can serve as the basis to inform human dose selection. The proposal for this session is to provide an overview of tropical diseases and translational models to support antiparasitic drug development. Selected experts/scientists/physicians from academia, FDA, pharmaceutical industry, and nonprofit organization(s) will present the challenges and opportunities for antiparasitic drug discovery and show practical examples of translational PK/PD models to support decision making in antiparasitic drug development.


Learning Objectives

- The past, present and future of drug development for tropical diseases
- Model-informed drug development to accelerate entry of new chemical entities into efficacy studies in endemic areas
- Understand the use of pharmacometric approaches to support decision making and guide antiparasitic drug development strategies in pediatrics.
Session Speakers and Presentations

Steve Kern - Towards establishment of quantitative framework to address drug development questions in global health setting
Presentation

Jorg J. Mohrle - PK/PD modeling for malaria
The proposed presentation will demonstrate how PK/PD modelling will play an important role in the development of new antimalarial combination therapies to combat emerging drug resistance, simplify treatment regimens and ultimately contribute to malaria eradication. PK/PD modelling in anti-malaria drug development can accelerate the progress of new compounds into patient studies, reduce the number of patients on ineffective or excessive doses and demonstrate the contribution of individual drugs in combination therapy.

Luning (Ada) Zhuang - Dosage considerations for FDA approval of benznidazole in children with Chagas disease
This proposed presentation will provide a regulatory perspective on the development of an anti-parasitic drug against Chagas disease and discuss the retrospective analysis of historical efficacy and safety in children with Chagas disease by using this anti-parasitic drug as an example. The presentation will focus on the application of pharmacometric strategy to facilitate decision making on dose selection in the pediatric population of an age group based on limited data.

Vincent Madelain - Ebola viral dynamics in nonhuman primates: insights into virus immuno-pathogenesis and antiviral strategies
Poster abstract speaker - Poster W-053  Wednesday 8-9 AM