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PK/PD modeling and trial simulation for everyone

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Nowadays it is rare to see any FDA submission package without a Pharmacokinetics/Pharmacodynamics modeling component where some clinical trials were designed based on simulation. The current workflow is that an expert modeler provide model outputs and simulation about scenarios that he thinks are important to emulate future trials and decisions. Then, the decision maker might then ask for new more relevant scenarios to the current situation. This decision process is iterative where one simulated scenario might warrant another question/scenario that need to be tested until we reach a satisfactory decision. As such this involves sveral cycles of back and forth. All this results in bottlenecks cycles where the decision maker is waiting for simualtion results and where simulation scientists are waiting for decision maker to give them more scenarios to test. Why is this ? The simulation workflow is so complicated that only the person who built the underlying models and simulation scenarios can get useful answers. However, recent technological advances has enabled simulation scientists to build specialized user interfaces that enable decision makers to be part of the design team and ask questions and get answers on the fly. Today this is possible using web based responsive user interface A successful simulation exercice involve a mathematical modeler (e.g.pharmacometrician), a clinical trial expert, a therapeutic area expert (or a clinician) a computational/web developer expert and the clinical development decision maker. An example of the development of such an app for Tuberculosis will be demoed.

Biography

Mohamad Samer Mouksassi is an established pharmacometrician providing solutions for optimizing drug development and health care problems. He holds a clinical degree PharmD (Lebanese University), and postgraduate degrees in Biostatistics, Epidemiology and Pharmacokinetics Modeling and Simulation from University of Montreal, PQ, Canada. During his industry experience Samer's team successfully obtained several regulatory approvals for several therapeutic indications namely in pediatrics and rare diseases. More recently, Samer was the key analyst that led the efforts to successfully qualify an imaging biomarker for polycystic kidney disease. He continues to specialize in bringing therapeutic options for neglected diseases and vulnerable populations.

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