Abstract Template

Abstract Title: Quantitative Systems Pharmacology (QSP) can improve hypothesis generation and testing in Pharmaceutical R&D

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Abstract (not more than 300 words)

Quantitative Systems Pharmacology (QSP) is an approach to mechanistic mathematical modelling of human disease pathophysiology and drug pharmacology that integrates data from both clinical and non-clinical sources to build predictive models. The cycle of hypothesis generation and testing is an important driver in pharmaceutical R&D. However, hypothesis generation needs become more robust, by integrating a broader range of non-clinical and clinical data. QSP can be the means of integrating this data in a comprehensive and mechanistic manner, and thus generate rigorous biological/pharmacological hypotheses. Since these hypotheses are quantitative in nature, they are more rationally tested with clinical and non-clinical experimentation. This provides the opportunity to improve efficiency and productivity in pharmaceutical R&D. An example will be presented in which a QSP model of autoimmune disease is used to generate hypotheses about a therapeutic mechanism of action that are investigated in non-clinical and clinical experiments.

Keywords— *Modelling, Pharmaceutical R&D, Pharmacology, Systems Biology*

Professional Biography (100-150 words)

Tarek Leil is currently the head of the Quantitative Clinical Pharmacology (QCP) group within Clinical Pharmacology and Pharmacometrics (CP&P) at Bristol-Myers Squibb (BMS). The QCP group at BMS uses model based approaches, including quantitative systems pharmacology (QSP), physiologically based PK (PBPK), and model-based meta-analysis (MBMA), to integrate clinical and non-clinical data using models that summarize knowledge and generate actionable predictions. These predictions can be used to help with decision making in drug discovery and clinical development, to optimize the design of patient clinical trials, and to facilitate communications with regulatory authorities. Prior to joining BMS in 2011, Dr. Leil worked at Pfizer in the Department of Clinical Pharmacology. Dr. Leil and the QCP group have numerous publications and presentations demonstrating the utility of Pharmacometrics and Systems Pharmacology in Pharmaceutical R&D.



Any Comments: