



Pfizer report demonstrates value of conducting virtual studies of drug-drug interactions

Sheffield, UK, 10th June 2008 A new report to appear in the British Journal of Clinical Pharmacology shows how pharmaceutical companies can use modelling and simulation to predict clinically significant drug-drug interactions before undertaking human studies. Scientists at Pfizer Global Research and Development (Sandwich, Kent) have used the Simcyp Simulator to predict the extent of drug-drug interactions for Maraviroc, which is used in combination with other medications in the treatment of HIV.

The research group used the Simcyp Simulator, together with *in vitro* data, to predict *in vivo* outcomes. The results of this 'virtual' study were then compared with observed clinical data. The simulations were found to be in good agreement with the clinical results, which led to the conclusion that validated models of drug-drug interactions within Simcyp allow for the prediction of other metabolic drug-drug interactions without the need for a clinical study.

The report stated: *"Simcyp has successfully simulated the extent of clinical interactions with CYP3A4 inhibitors, further validating this software as a good predictor of CYP-based drug-drug interactions."*

Professor Amin Rostami-Hodjegan, Director of Research and Development at Simcyp, commented: *"We are very pleased that Pfizer, the world's largest pharmaceutical company, is taking full advantage of its routine in vitro data by successfully using the Simcyp Simulator to accurately predict drug-drug interactions. Clearly, the combination of high quality modelling and simulation plus high quality in vitro data is a powerful tool for streamlining drug development. Simcyp simulations, which draw from unique databases of biological information, are increasingly being used to improve the design of human studies, identify the characteristics of individuals most at risk from adverse drug reaction, and even avoid unnecessary and costly clinical studies."*

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About Simcyp

Simcyp Limited provides a platform for the modelling and simulation of drug absorption, distribution, metabolism and excretion (ADME) in virtual populations. This enables individuals at extreme risk from adverse reaction to be identified, and unnecessary drug exposure to human volunteers and animals to be minimised. The limitations of candidate compounds, including potential drug-drug interactions, can be assessed and managed prior to human studies, allowing better focus of drug development resources.

The Simulator is licensed to the twenty members of the Simcyp Consortium, which includes nine of the top ten pharmaceutical companies worldwide. Academic licenses to support key research related to drug development have been granted to centres of excellence in Europe, the USA and Japan. Simcyp also provides consultancy services, runs education programmes, and conducts internationally recognised leading-edge research and development.

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