



Simcyp releases updated Paediatric Simulator for evaluation of medicines in children

Sheffield, UK, 14th April 2008. Simcyp, the leader in predictive pharmacokinetics, today announces the release of the 2008 version of the Simcyp Paediatric Simulator, a modelling and simulation platform which provides valuable information relevant to first-time dosing decisions and the design of clinical studies in infants, neonates and children.

Simcyp Paediatric models pharmacokinetic behaviour over any age range using *in vitro* data routinely generated during drug discovery and development. This allows 'what-if' questions to be explored in the safety of a computer. The flexibility of the platform also allows predictions to be made from adult *in vivo* values by retrograde modelling.

The Simcyp simulations are carried out in virtual populations of children, rather than a single individual. This produces 'real world' predictions and can identify the characteristics of patients at the extremes of exposure.

"Traditional dosing decisions have often been taken under the false assumption that young children are simply little adults," according to Dr Trevor Johnson, Senior Pharmacist at Sheffield Children's Hospital and Senior Scientist at Simcyp. *"This model takes into account the many changes in pharmacokinetics which occur as a result of organ maturation and changes in body composition and drug elimination pathways."*

Dr Johnson commented: *"Fewer than 50% of children's medicines have actually been tested in an appropriate age group. Simcyp Simulations allow a clinical study in children to become 'confirmatory' rather than 'exploratory', reducing unnecessary drug exposure. This is crucial now that EU regulations insist that paediatric data be included in all applications for new medicinal products."*

Simcyp Paediatric 2008 is available to Simcyp Consortium members as a module to integrate with the Simcyp Population-based ADME Simulator.

– Ends –

About Simcyp

Simcyp Limited provides a platform for the modelling and simulation of drug absorption, distribution, metabolism and elimination (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 members of the Simcyp Consortium, which currently includes 9 of the top 10 pharmaceutical companies worldwide. Academic licenses to support research activities are also granted to Centres of Excellence in Europe, USA and Japan. In addition, Simcyp offers consultancy services, runs education programmes, and conducts internationally recognised leading-edge research and development.

For further information, please visit www.simcyp.com.

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