

### **1) Pharmazeutische Zeitung - February 28, 2008**

For ten years, the American approval agency FDA has been investigating drugs in children after approval for adults. Professor Dr. Jeffrey S. Barrett of the Children's Hospital of Philadelphia, USA, reported that for 118 out of 300 drugs investigated so far the approved features had to be changed, in 25% because of serious side effects or substantial health impairments and in 20% because of lack of efficacy.

The Children's Hospital of Philadelphia is developing a "Pediatric Knowledge Database" (Pediatric Knowledgebase, PKB). This tool is to enable every physician to design an individual treatment regime and to estimate and visualize possible effects and risks associated with his decision through simulations, based on electronically saved medical reports and on information from medical databases.

### **Deutsche Apotheker Zeitung of March 3, 2008**

The in-silico simulation on the computer can close gaps in knowledge when clinical studies are difficult to carry out, states the American approval agency FDA. For ten years, it has been investigating drugs in children after approval in adults. Prof. Dr. Jeffrey S. Barrett from the Children's Hospital of Philadelphia, USA, reported that in 118 out of 300 drugs investigated, details of approval have been changed for children. Doses for children, for example, were changed in 17% of drugs, and for younger children in 55% of cases. New safety data was added in about every fifth drug. This allowed improvement in the safety of use, Barrett said.