

## **"Guide to Paediatric Drug Development and Clinical Research"**

**Klaus Rose and John van den Anker, editors, 2010, 221 pages, Karger, \$162**

**Review by Norman M. Goldfarb**

"Guide to Paediatric Drug Development and Clinical Research" provides a concise, yet comprehensive review of paediatric clinical research, taking advantage of the fact that paediatric drug development is mostly about testing adult drugs in children. The reader can expect to learn about the state of the enterprise: regulations, ethics, protocol design, informed assent/consent, etc. Practical "how to" tips are not explicit but can be deduced.

This book has been selected for  
[The First Clinical Research Bookshelf](#)  
Essential reading for clinical research professionals

Three chapters cover European, U.S. and Japanese paediatric regulations. Paediatric clinical research, like adult clinical research is becoming global. The essay about U.S. regulations notes that the authors' analysis of 99 drugs studied under the Best Pharmaceuticals for Children Act between 2002 and 2007 found that the U.S. provided 60% of the study subjects.

Anyone who has been a child probably recalls some reluctance in taking his or her medicine. ("Mother, shall we not?") The essay, "The Future of Oral Paediatric Formulations," describes emerging methods of drug administration. In one method, shaking the bottle liquefies the thixotropic gel so it can be poured and measured; it then returns to a gel state in the spoon, which is more palatable to children. In another, the inside of a drinking straw is coated with taste-masked granules of the drug.

The book includes 31 essays by 63 contributors in eight sections:

- Introduction (1 essay)
- The Global Framework of Paediatric Drug Development (7 essays)
- Paediatric Clinical Pharmacology (2 essays)
- Practical and Ethical Challenges (6 essays)
- General and Specific Scientific Challenges (6 essays)
- Disease-Specific Challenges (8)
- Future of the Paediatric Pharmaceutical Market (1 essay)

The book is available in bookstores.

### **Reviewer**

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