

"Guide to Paediatric Clinical Research"

Klaus Rose and John N. van den Anker, editors, 2007, 137 pages, Karger, \$92.00

Review by Norman M. Goldfarb

"Guide to Paediatric Clinical Research" covers a broad range of important topics in pediatric clinical research. Although the regulatory chapters focus on Europe, most of the chapters apply worldwide. The book is essential reading for anyone who designs or conducts clinical trials with children.

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

Pediatric research involves numerous challenges, such as:

- Treatment experience in adults (and animals) may poorly predict safety and efficacy in children.
- Availability of suitable study subjects may be very limited.
- Children may assume that "study" refers to homework and "trials" happen to bad people.
- Children may not understand study activities. For example, they may think that EKGs work by passing dangerous electricity through the body.
- For better or worse, children may be strongly influenced by their parents. Teenagers may automatically reject the course recommended by their parents.
- Age may not be a good indicator of ability to assent; medical experience may be more relevant.
- Required explanations of contraception may be inappropriate for some children.
- Small children may be embarrassed when they have trouble signing their name because they have learned to hold pencils but not pens.
- Children can easily change their mind about continuing in a study, for unanticipated reasons.
- Needlephobia is relatively common in children, often for good reason. If triggered during a clinical trial, it may jeopardize their future healthcare.
- Studies with children of different ages may require multiple formulations, (e.g., tablet and liquid) of the test article.

The book consists of 15 essays:

- Europe's Path towards Better Medicines for Children
- The European Academy of Paediatrics (EAP/CESP) and Its Demand for More Clinical Research
- Paediatric Medicines: A View from Patient Organizations
- Paediatric Drug Development – Historical Background of Regulatory Initiatives
- ICH E11: Clinical Investigation of Medicinal Products in the Paediatric Population
- Ethical Challenges of Clinical Research in Children
- Consent and Assent in Paediatric Clinical Trials
- Collecting Blood and Tissue Samples in Paediatric Clinical Trials
- Paediatric Formulations

- Central Laboratory in Paediatric Clinical Trials
- Study and Protocol Design for Paediatric Patients of Different Ages
- Innovative Methodologies for Drug Evaluation in Children
- Challenges in the Research of Very Small Children
- Clinical Research for Infant Nutrition
- Conclusions: Paediatric Drug Development in the Global Context

The book is available in bookstores.

Reviewer

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.