Illuminating the road to safe and effective drugs

Guide to Paediatric Clinical Research

Editors:
Klaus Rose, John N. van den Anker

As off-label use of medicines in children is no longer acceptable today, paediatric drug development is currently in transition from an almost exclusive academic specialty towards an integrated part of the global process that drives the development of new pharmaceuticals. US and EU governments have made it mandatory for the pharmaceutical industry to investigate medicines in children, thus exposing a multitude of different institutions to paediatric research. Written by exponents of the academia as well as the pharmaceutical industry, regulators and patient advocacy groups, this book explains the background of the US and EU paediatric legislations, gives an analysis of their probable short-, mid- and long-term impact, addresses key operational challenges in paediatric research, and develops a tentative vision where paediatric drug development needs to go.
Helping to understand the role of the different stakeholders, the spectrum of readers to profit from this book ranges from paediatricians, general medical personnel and pharmacologists to those involved in regulatory affairs and clinical trials, pharmaceutical company management, patient advocacy groups, ethical committees, politicians and interested lay persons.

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This book will be an indispensable companion for those conducting clinical trials and should have a fixed place in the library of every investigator and his staff.

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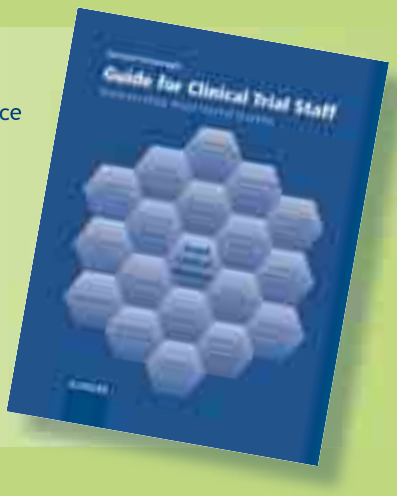

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