

Contents

1	Extrapolation of Preclinical Data into Clinical Reality – Translational Science <i>T. Singer</i>	1
2	Smarter Candidate Selection – Utilizing Microdosing in Exploratory Clinical Studies <i>P. Buchan</i>	7
3	The Applications of Biomarkers in Early Clinical Drug Development to Improve Decision-Making Processes <i>J. Kuhlmann</i>	29
4	Using Exposure – Response and Biomarkers to Streamline Early Drug Development <i>J. Venitz</i>	47
5	Experiences with Dose Finding in Patients in Early Drug Development: The Use of Biomarkers in Early Decision Making <i>S.R. Sultana, S. Marshall, J. Davis, B.H. Littman</i>	65
6	Genotype and Phenotype Relationship in Drug Metabolism <i>I. Roots, G. Laschinski, F. Arjomand-Nahad, J. Kirchheiner, D. Schwarz, J. Brockmöller, I. Cascorbi, T. Gerloff</i>	81

7	Clinical Trials in Elderly Patients <i>S.H.D. Jackson</i>	101
8	Dose Finding in Pediatric Patients <i>G. Henze</i>	111
9	Integration of Pediatric Aspects into the General Drug Development Process <i>K. Rose</i>	123
10	Current Stumbling Blocks in Oncology Drug Development <i>C.D. Gimmi</i>	135
11	Exploratory IND: A New Regulatory Strategy for Early Clinical Drug Development in the United States <i>N. Sarapa</i>	151
12	Ethnic Aspects of Cancer Trials in Asia <i>T.W.T. Leung</i>	165
13	Evaluation of the Effect on Cardiac Repolarization (QTc Interval) of Oncologic Drugs <i>J. Morganroth</i>	171
14	The Role of PET Scanning in Determining Pharmacoselective Doses in Oncology Drug Development <i>P. Price</i>	185
15	Biometrical Aspects of Drug Development <i>D. Machin, S-B. Tan</i>	195
16	Preventing Postmarketing Changes in Recommended Doses and Marketing Withdrawals <i>C. Peck</i>	209
	Previous Volumes Published in This Series	217

Appropriate Dose Selection - How to Optimize Clinical
Drug Development

Venitz, J.; Sittner, W. (Eds.)

2007, XVI, 216 p., Hardcover

ISBN: 978-3-540-27867-2