

Contents

IX Introduction

XIII The Editors

xv Authors' Addresses

The Global Framework of Paediatric Drug Development

1 Europe and the Path to Better Medicines for Children

Ramet, J. (Edegem); Lehman, B. (Bonn); Rose, K. (Basel)

6 European Union Paediatric Regulation: Theory and Practice

Wright, E. (Brussels); Rose, K. (Basel)

12 United States Paediatric Legislation Impact on Paediatric Drug Studies

Rodriguez, W. (Rockville, Md.); Maldonado, S. (Raritan, N.J.)

15 Facilitation of Paediatric Research in Japan

Nakamura, H.; Ozaki, M. (Tokyo)

23 Ethical Imperatives in Medical Research on Child Subjects – Reflections of a Past President of the World Medical Association

Appleyard, W.J. (Kent)

32 Paediatric Clinical Research: The Patients' Perspective

Kent, A. (London/Brussels); Oosterwijk, C. (Brussels/Soest); Poortman, Y. (The Hague)

40 Providing Global Access to Essential Medicines for Children – The WHO Better Medicines for Children Programme

Hoppu, K. (Helsinki); Hill, S. (Geneva)

Paediatric Clinical Pharmacology

46 Paediatric Clinical Pharmacology: From Bench to Bedside

van den Anker, J.N. (Washington, D.C./Rotterdam)

51 Role of Clinical Pharmacology in the Development of Paediatric Clinical Development Plans

Reigner, B.; Ricci, B.M.; Liohier d'Ardhuy, X. (Basel)

60 Guide through the EMA Paediatric Website

Rose, K. (Basel); Granzer, U. (Munich); Della Pasqua, O. (Stockley Park)

64 Paediatric Homework: Paediatric Investigation Plan Key Elements

Rose, K. (Basel); Della Pasqua, O. (Stockley Park)

71 Ethics in Paediatric Research: Three Years after the Introduction of the European Regulation

Matthys, D. (Ghent); Rose, K. (Basel)

75 Consent and Assent in Paediatric Clinical Trials

Simar, M.R. (Austin, Tex.); Fowler, P.A. (Hertford)

83 Study and Protocol Design for Paediatric Patients of Different Ages

Della Pasqua, O. (Stockley Park); Zimmerhackl, L.B. (Innsbruck); Rose, K. (Basel)

97 Points to Consider when Planning the Collection of Blood or Tissue Samples in Clinical Trials of Investigational Medicinal Products in Children, Infants and Neonates

Hawcutt, D.B.; Rose, A.C. (Liverpool); Fuerst-Recktenwald, S. (Basel); Nunn, T.; Turner, M.A. (Liverpool)

General and Specific Scientific Challenges

111 What Constitutes Adequate Strength of Evidence?

Day, S. (Welwyn Garden City)

117 Paediatric Formulations

Tuleu, C. (London); Solomonidou, D. (Basel); Breitzkreutz, J. (Düsseldorf)

128 The Future of Oral Paediatric Formulations

Bar-Shalom, D. (Copenhagen)

131 Paediatric Pharmacovigilance in Clinical Research and Drug Development

Mentzer, D. (Langen); Day, S. (Welwyn Garden City)

138 Role of Non-Clinical Safety Assessment in Paediatric Drug Development

De Schaepdrijver, L.M. (Beerse)

144 Paediatric Critical Care

Goldstein, B. (Clinton, N.J./New Brunswick, N.J.); Nelson, R.M. (Silver Spring, Md.); Nadel, S. (London)

Disease-Specific Challenges

155 Research and Drug Development in Paediatric Oncology

Massimini, G.; Rose, K. (Basel); Vassal, G. (Villejuif); Pritchard-Jones, K. (Sutton)

160 Paediatric Cancer Treatment in Africa

Renner, L.A. (Accra)

164 Paediatric Clinical Research in Immunology and Inflammation

Bolte, C. (Basel); Senolt, L. (Prague); Gay, S. (Zurich)

170 Clinical Trials of Anti-Infective Agents in Paediatrics

Lutsar, I. (Tartu); Friedland, I. (Lexington, Mass.)

178 Obesity in Children

Hebebrand, J. (Essen)

187 Familial Dyslipidaemia in Children

Kusters, D.M.; Avis, H.J.; Vissers, M.N.; Hutten, B.A.; Kastelein, J.J.P.; Wiegman, A. (Amsterdam)

196 Paediatric Anti-Hypertensive Clinical Trials and Various Factors Influencing Trial Success or Failure

Li, J.S.; Benjamin, D.K., Jr. (Durham, N.C.); Severin, T. (Basel); Portman, R.J. (Princeton, N.J.)

206 Paediatric Vaccination Trials

Ceddia, F. (Wavre); Podda, A. (Siena); Vesikari, T. (Tampere)

Future of the Paediatric Pharmaceutical Market

212 Future of the Paediatric Pharmaceutical Market

Grek, V. (Paris); Rose, K. (Munich)

215 Author Index

216 Subject Index