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Drug Development in Children: Clinical Advances and Perspectives

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Message from the Guest Editors

Dear Colleagues,

The lack of progress in drug development for children is a common issue worldwide. Children respond to pharmaceuticals differently from adults in more than a few cases, with wide variation from neonates to adolescents, requiring responses and studies appropriate to each age group, including in terms of pharmaceutical dosage forms and pharmacokinetics. In addition, there are few opportunities to collect information on pediatric patients, and there is a lack of evidence. In order to assess risks and benefits based on medical and pharmacological evidence, ICH Guideline E11 (Guidance on Clinical Studies of Medicinal Products in Pediatric Populations) and E11(R1) recommend the use of optimal methods for collecting information on pediatric experiences.

We would like to collect and share the latest findings of clinical research, regulatory science, investigations of clinical issues, pediatric formulation development, and the off-label use of drugs in children, as well as a wide range of recommendations related to issues of children, in order to make further progress in drug development.