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Review on Drug Evaluation Methods

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Abstract: The pharmacokinetics and pharmacodynamics of drugs are different in adult and paediatric populations, the latter being particularly heterogeneous. These differences in pharmacokinetics and pharmacodynamics justify specific studies but raise a number of ethical and practical issues. The main practical difficulties to circumvent while performing clinical studies in children are the invasiveness of the procedures and the obstacles to patient recruitment. The invasiveness related to pain/anxiety and blood loss precludes the performance of classical pharmacokinetic studies in children in many instances, particularly in neonates and infants. Population approaches, which rely on pharmacokinetic-pharmacodynamic modelling, are particularly appealing in paediatric populations because these models can cope with sparse data. The relevance of population approaches to investigation of the dose-concentration-effect relationships and to qualitative/quantitative assessment of factors that may explain interindividual variability has already been emphasized.

Keywords: Drug Evaluation

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