



## Appropriate dose selection : how to optimize clinical drug development /

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Monografía

Optimal dose individualization has become more important in improving clinical efficacy and safety, given the variability in drug response, e.g., due to concurrent illnesses or co-medications. Therefore, the role of optimal dose finding in early clinical drug development so as to maximize successful clinical use is emphasized. The continued use of biomarkers -- based on the (known) pharmacology of the drug and/or biology of the underlying disease -- along with exposure--response evaluation throughout all phases of drug development can quantitatively integrate clinical pharmacology knowledge, provide early proof of concept, and help in rational dose selection and rational drug product labeling for clinical use

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**Contenido:** Extrapolation of Preclinical Data into Clinical Reality -- Translational Science -- Smarter Candidate Selection -- Utilizing Microdosing in Exploratory Clinical Studies -- The Applications of Biomarkers in Early Clinical Drug Development to Improve Decision-Making Processes -- Using Exposure -- Response and Biomarkers

to Streamline Early Drug Development -- Experiences with Dose Finding in Patients in Early Drug Development: The Use of Biomarkers in Early Decision Making -- Genotype and Phenotype Relationship in Drug Metabolism -- Clinical Trials in Elderly Patients -- Dose Finding in Pediatric Patients -- Integration of Pediatric Aspects into the General Drug Development Process -- Current Stumbling Blocks in Oncology Drug Development -- Exploratory IND: A New Regulatory Strategy for Early Clinical Drug Development in the United States -- Ethnic Aspects of Cancer Trials in Asia -- Evaluation of the Effect on Cardiac Repolarization (QTc Interval) of Oncologic Drugs -- The Role of PET Scanning in Determining Pharmacoselective Doses in Oncology Drug Development -- Biometrical Aspects of Drug Development -- Preventing Postmarketing Changes in Recommended Doses and Marketing Withdrawals

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