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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