

Pharmacokinetics: From discovery to precision medicine.

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Introduction

This article delves into the unique pharmacokinetic characteristics of biologics, especially monoclonal antibodies, highlighting their complex absorption, distribution, metabolism, and excretion pathways which differ significantly from small molecule drugs. It explores how factors like target-mediated drug disposition, immunogenicity, and formulation impact their pharmacokinetics and clinical outcomes, emphasizing the considerations for biosimilar development and evaluation[1].

This review explores the population pharmacokinetics and pharmacodynamics of rivastigmine, a drug used in Alzheimer's disease. It highlights how understanding inter-individual variability in drug response, through advanced modeling techniques, is crucial for optimizing dosing strategies and achieving better therapeutic outcomes, moving towards more personalized medicine in neurodegenerative conditions[2].

This comprehensive review examines drug-drug interactions (DDIs) in critically ill patients, a population highly susceptible to complex polypharmacy. It thoroughly discusses how pharmacokinetic alterations—like changes in absorption, distribution, metabolism, and excretion—contribute to DDIs in this vulnerable group, providing insights into predicting and managing adverse events in intensive care settings[3].

This article investigates the pivotal role of pharmacogenomics in tailoring drug dosages, specifically focusing on opioids. It explains how genetic variations can significantly alter pharmacokinetic parameters, such as drug metabolism by cytochrome P450 enzymes, which then dictates individual responses and the risk of adverse effects, paving the way for more precise and safer pain management[4].

This article emphasizes the foundational role of pharmacokinetics throughout the early phases of drug discovery and development. It highlights how integrating ADME (absorption, distribution, metabolism, excretion) principles early on helps in candidate selection, dose prediction, and toxicity assessment, ultimately accelerating the progression of promising compounds and minimizing late-stage failures[5].

This review provides an update on the clinical pharmacokinetics of novel anti-cancer agents, acknowledging the increasing complexity in their mechanisms of action and metabolism. It addresses challenges in accurately characterizing the PK profiles of these drugs, which is essential for optimizing dosing regimens, minimizing toxicity, and maximizing therapeutic efficacy in diverse cancer patient populations[6].

This article highlights the unique challenges in pediatric pharmacokinetics, emphasizing the significant developmental changes in ADME processes from neonates to adolescents. It discusses the critical need for age-appropriate pharmacokinetic studies to ensure safe and effective drug dosing in children, outlining recent advances and strategies to overcome historical hurdles in pediatric drug development[7].

This review explores the pharmacokinetics of various bioactive natural products, emphasizing their potential as sources for new drug discovery. It details how the complex chemical structures and often poor bioavailability of these compounds present unique challenges in understanding their ADME profiles, underscoring the necessity of robust pharmacokinetic studies to translate traditional knowledge into modern therapeutic agents[8].

This article explores how pharmacokinetic modeling is essential for achieving precision dosing, moving away from 'one-size-fits-all' drug regimens. It discusses the application of population PK and Bayesian forecasting to individualize therapy, ensuring optimal drug exposure for each patient while minimizing toxicity and maximizing therapeutic efficacy, a core tenet of precision medicine[9].

This article showcases physiologically based pharmacokinetic (PBPK) modeling as an increasingly vital tool in modern drug development and regulatory processes. It elucidates how PBPK models integrate drug-specific, system-specific, and population-specific parameters to predict drug behavior across various scenarios, aiding in dose optimization, DDI predictions, and extrapolating data to special populations, thereby reducing the need for extensive clinical trials[10].

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Conclusion

Pharmacokinetics (PK) is fundamental to the entire drug lifecycle, from initial discovery to advanced clinical application. Integrating ADME (absorption, distribution, metabolism, excretion) principles early on is key for selecting viable drug candidates, forecasting dosages, and evaluating toxicity, which helps streamline drug development and prevent late-stage failures. Drug-specific characteristics significantly influence PK profiles; for example, biologics like monoclonal antibodies have complex pathways that differ markedly from small molecule drugs, necessitating unique considerations for biosimilar development. The field also faces challenges in characterizing the PK of novel anti-cancer agents and bioactive natural products, which often have intricate structures and variable bioavailability. Special patient populations, such as critically ill patients susceptible to drug-drug interactions (DDIs) due to polypharmacy, and pediatric patients undergoing rapid developmental changes in ADME processes, require specialized PK studies to ensure safe and effective dosing. To address these complexities, advanced methodologies are employed. Population Pharmacokinetics and Bayesian forecasting are crucial for understanding inter-individual variability and enabling precision dosing, moving beyond 'one-size-fits-all' regimens. Additionally, Pharmacogenomics offers insights into how genetic variations, particularly in drug-metabolizing enzymes, impact individual responses and inform tailored opioid dosages for safer pain management. Physiologically Based Pharmacokinetic (PBPK) modeling acts as a powerful tool, predicting drug behavior across various scenarios and aiding regulatory decisions by integrating drug, system, and population-specific parameters. All told, these diverse pharmacokinetic insights and modeling techniques are essential for optimizing therapeutic outcomes, minimizing adverse effects, and advancing individualized medicine.

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