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Abstract. Intense competitive pressure may require short development times and can result in approval of safe and effective dose regimens that are suboptimal. Well-designed phase IV studies can lead to identification of doses and dose regimens that may improve efficacy and/or reduce risks (resulting in an improved risk/benefit ratio).

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Dose Optimization in Drug Development
For lisinopril, a large phase IV trial showed that a dose much higher than that widely used was necessary to reduce mortality in patients with congestive heart failure. Reduced risk: Captopril, the first angiotensin-converting enzyme (ACE) inhibitor to reach the market was initially marketed at too high a dose. A reduction in dose markedly reduced the risk of nephrotoxicity while maintaining anti-hypertensive efficacy.

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Obstacles to Dose Optimization in Early Stage Cancer Drug ...
Today drug discovery involves screening hits, medicinal chemistry, and optimization of hits to reduce potential drug side effects (increasing affinity and selectivity). Efficacy or potency, metabolic stability (half-life), and oral bioavailability are also improved in this step of the drug development process. Target Identification & Validation

Phases of Drug Development Process, Drug Discovery Process ...
Introduction: Identifying the optimized dosing regimen and algorithm is critical in the development of antibiotics. Suboptimal regimens and inappropriate choice of drug give rise to drug-resistant bacteria which have limited the therapeutic utility of many commercially available antimicrobial agents.

Pharmacokinetics and pharmacodynamics in antibiotic dose ...
Drug Development; Electronic Health Records; Emergency Medicine; End of Life; Environmental Health; Ethics; Facial Plastic Surgery; Foodborne Illness; Gastroenterology and Hepatology; Genetics and Genomics; Genomics and Precision Health; Geriatrics; Global Health; Guide to Statistics and Medicine; Guidelines; Hair Disorders; Health Care Delivery Models

Dose-Finding Trials: Optimizing Phase 2 Data in the Drug ...
Opportunities for clinical pharmacology and model-informed drug development during the COVID-19 pandemic. Applications in (left panel) dosage optimization of COVID-19 therapies, (middle panel) informing benefit/risk for clinical trial participants, and (right panel) mitigating impact of clinical trial disruptions, with a Totality of Evidence approach.

Challenges in Drug Development Posed by the COVID-19 ...
Johnson & Johnson launched a new late-stage trial in Britain on Monday to test a two-dose regimen of its experimental COVID-19 vaccine among thousands of volunteers, as the U.S. drugmaker expands ...

J&J starts two-dose trial of its COVID-19 candidate ...
Though the companies didn't take any money from the federal government for research and development for the drug, they reached a nearly \$2 billion agreement in July to supply 100 million doses to ...

Covid vaccine: Pfizer says drug 90% effective in blocking ...
A non-inferiority endpoint was chosen for the study to ensure that people were receiving sufficient dosing with Perjeta and Herceptin as compared to the established IV doses at the same treatment intervals.7,8 About PhesgoPhesgo is a new fixed-dose subcutaneous (SC) formulation that combines the same monoclonal antibodies as Perjeta and Herceptin with Halozyme Therapeutics' Enhance® drug ...

CHMP recommends EU approval of Roche's Phesgo (fixed-dose ...
The U.S. drugmaker plans to enrol up to 30,000 participants for the study and run it in parallel with a one-dose trial with as many as 60,000 volunteers that began in September.