Multiple Ascending Dose Study

KARTER WIGGINS

Physiologically Based Pharmacokinetic (PBPK) Modeling and Simulations Springer Nature
The aim of this study was to evaluate the safety, pharmacokinetics, and clinical response of brodalumab (AMG 827), a human, anti-IL-17 receptor A (IL-17RA) monoclonal antibody in subjects with moderate-to-severe rheumatoid arthritis (RA).
Stephens' Detection and Evaluation of Adverse Drug Reactions John Wiley & Sons
Presents the complicated process of CNS drug development in a way that is engaging and informative for professionals and students.
Modern CNS Drug Discovery Springer
Bone Resorption: New Insights for the Healthcare Professional: 2011 Edition is a ScholarlyPaper™ that delivers timely, authoritative, and intensively focused information about Bone Resorption in a compact format. The editors have built Bone Resorption: New Insights for the Healthcare Professional: 2011 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Bone Resorption in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Bone Resorption: New Insights for the Healthcare Professional: 2011 Edition has been produced by the world’s leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.
Pharmacokinetics and Adverse Effects of Drugs BoD – Books on Demand
The book, intended for biomedical researchers, attempts to foster

a comprehensive understanding of the elements that impact scientific research, such as clinical trial design, communication, and publication methods. It introduces the process of idea generation and creative/critical thinking, leading to the development of key concepts that coalesce into theoretical constructs and working hypotheses. The book systematically delineates research phases associated with a bench-to-bedside translational approach, providing the full depth and breadth of drug discovery and development: design, synthesis, and optimization of drug candidates interacting with targets linked to diseases, as well as clinical trial design to acquire substantial evidence of efficacy and safety for candidate drugs in the target patient population. New and evolving topics such as artificial intelligence, machine and deep learning, drug repurposing approaches, and bioinformatics, are incorporated into the text as these features are becoming integrated into drug research and development. Additionally, it covers publication strategies, including literature search, manuscript preparation, data presentation, relevant discussion, editorial processes, elements of peer review, and bibliometrics. Finally, the book addresses grantsmanship, key strategies for building effective networks, mentorships, maintaining research integrity, and forging career advancement opportunities, including entrepreneurship.

Dictionary of Pharmaceutical Medicine Thakur Publication Private Limited

If you have ever wondered when visiting the pharmacy how the dosage of your prescription is determined this book will answer your questions. Dosing information on drug labels is based on discussion between the pharmaceutical manufacturer and the drug regulatory agency, and the label is a summary of results obtained from many scientific experiments. The book introduces the drug development process, the design and the analysis of clinical trials. Many of the discussions are based on applications of statistical methods in the design and analysis of dose response studies. Important procedural steps from a pharmaceutical industry perspective are also examined.

Pharmacology-I (English Edition) Springer Nature

In 1775, the physician and botanist William Withering (1741-99) was informed of a folk cure for dropsy that had as its active ingredient the plant foxglove (Digitalis purpurea). Ten years later, after thorough trials on more than 150 patients, Withering published this monograph on the medicinal applications of the plant, not least to keep less experienced doctors from administering it to patients without the proper caution, given the plant's toxicity. Withering was the first doctor to employ foxglove as a remedy for congestive heart failure, which is now the primary disease treated by foxglove-derived pharmaceuticals, and the results from his trials broadly reflect those produced by modern physicians. Withering's first major publication, A Botanical Arrangement of All the Vegetables Naturally Growing in Great Britain (1776), which includes observations on the medicinal applications of British plants, is also reissued in this series.

Alzheimer's Disease II Oxford Desk Reference

Drug Discovery and Evaluation has become a more and more difficult, expensive and time-consuming process. The effect of a new compound has to be detected by in vitro and in vivo methods of pharmacology. The activity spectrum and the potency compared to existing drugs have to be determined. As these processes can be divided up stepwise we have designed a book series "Drug Discovery and Evaluation" in the form of a recommendation document. The methods to detect drug targets are described in the first volume of this series "Pharmacological Assays" comprising classical methods as well as new technologies. Before going to man, the most suitable compound has to be selected by pharmacokinetic studies and experiments in toxicology. These preclinical methods are described in the second volume „Safety and Pharmacokinetic Assays". Only then are first studies in human beings allowed. Special rules are established for Phase I studies. Clinical pharmacokinetics are performed in parallel with human studies on tolerability and therapeutic effects. Special studies according to various populations and different therapeutic indications are necessary. These items are covered in the third volume: „Methods in Clinical Pharmacology".

Adaptive and Flexible Clinical Trials Springer Science & Business Media

Provides a definitive overview of the complex ecosystem facilitating Alzheimer's Disease drug research and development. Demonstrates a drug's journey from in the lab, clinical trial testing, regulatory review, and marketing by pharmaceutical companies. Details the use of artificial intelligence, clinical trial management, and financing models.

Biotechnology Fundamentals John Wiley & Sons

Among neurodegenerative diseases, those that lead to a state of dementia are the aim of several investigations. Dementia is a chronic disease the prevalence of which is increasing worldwide. The number of dementia patients in the world is approximately 50 million, and it is estimated that the number of patients will reach 131.5 million by 2050. This increase will be accompanied by a significant increase in medical expenditures and other expenses, especially for elderly patients. Therefore, the maintenance cost of dementia in the future is expected to be quite high. For this reason, several investigations aim, firstly, to describe the key mechanisms involved in the origin of dementia and, secondly, to establish preventive and therapeutic strategies in order to understand and mitigate this debilitating pathology. This volume of Frontiers in Clinical Drug Research - Dementia explores the current comorbidities that cause cognitive impairment and the current management alternatives for clinical cases of dementia. The reviews contributed in these volume will provide readers with a current perspective on the subject. The topics covered in this volume include: - Comorbidities inducing mild cognitive impairment - an evaluation of the risk caused by some pathological conditions - Tau-targeted therapy in Alzheimer's disease - history and current state - Emerging nanotherapeutic strategies in Alzheimer's disease - Implication of dehydroepiandrosterone on dementia related to oxidative stress - Polyphenol compounds as potential therapeutic agents in Alzheimer's disease The volume is a timely update on dementia treatment for clinical physicians, neurologists, gerontologists, pharmaceutical and medicinal chemistry researchers, and physiologists.

Geriatric Neurology Springer Nature

This textbook provides a comprehensive overview of the currently used concepts, approaches and technologies in the discovery and development of new treatments for the full spectrum of disorders of the central nervous system. It guides the reader through all essential steps, from finding an innovative idea, to the registration of a new drug. Divided into four sections, the book starts by presenting a broad perspective on current approaches in central nervous system (CNS) drug discovery. The second section addresses the generation of ideas for the identification of targets and novel treatment strategies; covers core functions in early discovery, and provides an example of a novel treatment paradigm: brain stimulation. The third section highlights strategies and technologies in translational CNS drug discovery. In an effort to bridge the gap between discovery and clinical development, it also covers brain imaging, EEG and cognitive testing approaches. The fourth section extensively

discusses the clinical phase of drug development, covering the basics of early clinical testing for psychopharmacological drugs. The book's final chapter addresses the registration for newly developed drugs. Written by experts from academia and industry, the book covers important basics and best practices, as well as recent developments in drug discovery. Offering in-depth insights into the world of drug development, it represents essential reading for early researchers who want to prepare for a career in drug discovery in academia or industry.

An Account of the Foxglove, and Some of Its Medical Uses CRC Press

Today we witness an eventful time in which the powerful new forces of genomics, information technology and economics are rapidly changing the science and art of medicine. This will require more specialization than ever before. However, there is also an increasing demand for an integrated approach, which is provided by the discipline of Clinical Pharmacology (CP). CP pursues a scientific goal by studying drug action in patients and volunteers, a clinical goal by administering appropriate drug therapy and a regulatory goal by assessing the risk/benefit ratio of drug candidates in drug development and reimbursement. This introduction to current topics of CP covers traditional topics of clinical drug research and trial methodology but also provides insight in current topics like genomics, imaging technology and issues in drug reimbursement. A number of concrete case studies in clinical drug research and development help to give a better understanding of the general principles of CP.

Hepatitis: New Insights for the Healthcare Professional: 2013 Edition John Wiley & Sons

Hepatitis: New Insights for the Healthcare Professional: 2013 Edition is a ScholarlyEditions™ book that delivers timely, authoritative, and comprehensive information about Diagnosis and Screening. The editors have built Hepatitis: New Insights for the Healthcare Professional: 2013 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Diagnosis and Screening in this book to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Hepatitis: New Insights for the Healthcare Professional: 2013 Edition has been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.

Research Advances in Alzheimer's Disease and Related Disorders Cambridge University Press

This extensively revised second edition provides an up-to-date and highly informative textbook on psoriasis. The understanding of the mechanisms behind the disease and the available treatment options have continued to develop rapidly in recent times, with this vital resource covering the latest in these management options, including targeted T-cell therapy, the use of immunomodulators, systemic therapies, and ultraviolet and laser therapy. In addition, it provides a detailed overview of the pathophysiology, comorbidities, epidemiology and triggers of the disease. Advances in Psoriasis: A Multisystemic Guide extensively details the scientific basis and practice management of psoriasis. It is therefore a vital resource for practicing and trainee dermatologists looking to develop their clinical knowledge of how to manage and treat these patients.

The Quintessence of Basic and Clinical Research and Scientific Publishing ScholarlyEditions

The detection and evaluation of adverse drug reactions is crucial for understanding the safety of medicines and for preventing harm in patients. Not only is it necessary to detect new adverse drug reactions, but the principles and practice of pharmacovigilance apply to the surveillance of a wide range of medicinal products. Stephens' Detection and Evaluation of Adverse Drug Reactions provides a comprehensive review of all aspects of adverse drug reactions throughout the life cycle of a medicine, from toxicology and clinical trials through to pharmacovigilance, risk management, and legal and regulatory requirements. It also covers the safety of biotherapeutics and vaccines and includes new chapters on pharmacogenetics, proactive risk management, societal considerations, and the safety of drugs used in oncology and herbal medicines. This sixth edition of the classic text on drug safety is an authoritative reference text for all those who work in pharmacovigilance or have an interest in adverse drug reactions, whether in regulatory authorities, pharmaceutical companies, or academia. Praise for previous editions "This book presents a comprehensive and wide-ranging overview of the science of pharmacovigilance. For those entering or already experienced in the pharmaceutical sciences, this is an essential work." - from a review in E-STREAMS "...a key text in the area of pharmacovigilance...extensively referenced and well-written...a valuable resource..." - from a review in The Pharmaceutical Journal

Toxicology CRC Press

Following a long period of comparative neglect, Alzheimer's disease has come to be a major focus of scientific research, and in recent years considerable progress has been made towards understanding the basic molecular mechanisms of the disease and toward developing diagnostic and therapeutic strategies. Here, the latest information on Alzheimer's disease is presented, including topics such as the mechanisms of degeneration of neurons with neurofibrillary tangles, the formation of brain amyloid in Alzheimer's disease, risk factors, diagnosis and pharmacological approaches. The chapters are of a high standard, reflecting the fact that the authors are internationally renowned in their own specialist field and the book will have a wide appeal to psychopharmacologists, neurologists, psychiatrists, neurobiologists and neurochemists who seek a broad overview of the present thinking in the field.

Translational Research Methods in Diabetes, Obesity, and Nonalcoholic Fatty Liver Disease Royal Society of Chemistry

Drug repurposing, or repositioning, is the development of existing drugs for new uses: given that 9 in 10 drugs that enter drug development are never marketed and therefore represent wasted effort, it is an attractive as well as inherently more efficient process. Three repurposed drugs can be brought to market for the same cost as one new chemical entity; and they can also be identified more quickly, an important benefit for patients whose diseases are progressing faster than therapeutic innovation. But repurposing also requires a fresh look at configuring pharmaceutical R&D, considering clinical, regulatory and patent issues much earlier than would otherwise be the case. In addition to new ways of thinking, the discovery of repurposing opportunities can take advantage of artificial intelligence techniques to match the perfect new use for an existing drug. This book provides an ideal introduction to the field of drug repurposing with contributions from world-renowned experts culminating in an excellent resource for any drug discovery or medicinal chemist.

Clinical Pharmacy Education, Practice and Research Academic Press

This dictionary defines various terms typically used in pharmaceutical medicine. A new, 4th edition includes adaptations of the text to the steadily increasing regulatory requirements,

particularly in the area of genetics/gene therapy, product quality (e.g., protection against falsified medicines) and of product safety (pharmacovigilance). Further evolving areas that are covered by the 4th edition are typical “grey zones” (health effects often borderline to medicinal products) such as cosmetics and dietary supplements where misleading information is prohibited on one hand but where any health claims need formal authorisation on the other. These but also other areas are reviewed and presented in an updated and – if justified – in an enlarged form.

Frontiers in Clinical Drug Research – Dementia: Volume 2 Springer

Part of the renowned Braunwald family of references, Clinical Lipidology: A Companion to Braunwald’s Heart Disease provides today’s clinicians with clear, authoritative guidance on the therapeutic management of patients with high cholesterol levels and other atherogenic lipid disorders. An invaluable resource for cardiologists, lipidologists, endocrinologists, and internal medicine physicians, this one-stop reference covers everything from basic science and the pathogenesis of atherothrombotic disease to risk assessment and the latest therapy options. Now fully updated from cover to cover, the 3rd Edition offers unparalleled coverage of lipidology in an accessible and user-friendly manner. Thoroughly covers the assessment, diagnosis, and treatment of patients with elevated levels of lipids and lipoproteins, including all the latest research-based recommendations, therapeutic breakthroughs, and related clinical advances. Presents the latest data on clinical guidelines, risk assessments, and established and emerging pharmacologic and nonpharmacologic therapies—all from internationally recognized experts in the field. Features condensed, streamlined content that focuses on clinical applications and applying concepts to the practice setting. Chapters have now been completely reorganized into sections on risk assessment; therapy; new and evolving therapeutic targets and platforms; and special populations. Includes new chapters on Polygenic Risk Scores; Inclisiran; Bempedoic Acid; Selective Peroxisome Proliferator–Activated Receptor–a Modulator: Pemafibrate; Evolving Therapeutic Targets: Lp(a), ANGPTL3, and ApoC-III; New Therapeutic Platforms: Gene Therapy and Genome Editing; and more. Contains new or expanded content on inflammation; genetic testing; troponins for risk assessment; statins and role of bile acid sequestrants, niacin, and fibrates; mAbs; CANTOS and CIRT; colchicine; IL-6; and cellular, molecular, and genetic therapy. Provides treatment algorithms throughout, as well as case vignettes that highlight the most common clinical questions in each chapter. Incorporates the latest guidelines from the AHA, ACC, ESC, and EAS, as well as future directions for ongoing research and emerging applications.

Biomedical Research John Wiley & Sons

A single source reference covering every aspect of biotechnology, Biotechnology Fundamentals, Second Edition breaks down the basic fundamentals of this discipline, and highlights both conventional and modern approaches unique to the industry. In addition to recent advances and updates relevant to the first edition, the revised work also covers ethics in biotechnology and discusses career possibilities in this growing field. The book begins with a basic introduction of biotechnology, moves on to more complex topics, and provides relevant examples along the way. Each chapter begins with a brief summary, is illustrated by simple line diagrams, pictures, and tables, and ends with a question session, an assignment, and field trip information. The author also discusses the connection between plant breeding, cheese making, in vitro fertilization, alcohol fermentation, and biotechnology. Comprised of 15 chapters, this seminal work offers in-depth coverage of topics that include: Genes and Genomics Proteins and Proteomics Recombinant DNA Technology Microbial Biotechnology Agricultural Biotechnology Animal Biotechnology Environmental Biotechnology Medical Biotechnology Nanobiotechnology Product Development in Biotechnology Industrial Biotechnology Ethics in Biotechnology Careers in Biotechnology Laboratory Tutorials Biotechnology Fundamentals, Second Edition provides a complete introduction of biotechnology to students taking biotechnology or life science courses and offers a detailed overview of the fundamentals to anyone in need of comprehensive information on the subject.

Burger's Medicinal Chemistry, Drug Discovery and Development, 8 Volume Set Cambridge University Press

Physiologically Based Pharmacokinetic (PBPK) Modeling and Simulations The first book dedicated to the emerging field of physiologically based pharmacokinetic modeling (PBPK) Now in its second edition, Physiologically Based Pharmacokinetic (PBPK) Modelling and Simulations: Principles, Methods, and Applications in the Pharma Industry remains the premier reference book throughout the rapidly growing PBPK user community. Using clear and concise language, author Sheila Annie Peters connects theory with practice as she explores the vast potential of PBPK modeling for improving drug discovery and development. This fully updated new edition covers key developments in the field of PBPK modelling and simulations that have emerged in recent years. A brand-new section provides case studies in different application areas of PBPK modelling, including drug-drug interaction, genetic polymorphism, renal impairment, and pediatric extrapolation. Additional chapters address topics such as model-informed drug development (MIDD) and expose readers to a wide range of current applications in the field. Throughout the book, substantially revised chapters simplify complex topics and offer a balanced view of both the opportunities and challenges of PBPK modelling. Providing timely and comprehensive coverage of one of the most exciting new areas of pharmaceutical science, this book: Describes the principles behind physiological modeling of pharmacokinetic processes, inter-individual variability, and drug interactions for small molecule drugs and biologics Features a wealth of new figures and case studies of the applications of PBPK modelling along the value chain in drug discovery and development Reflects the latest regulatory guidelines on the reporting of PBPK modelling analysis Includes access to a new companion website containing code, datasets, explanations of case examples in the text, and discussion of key developments in the field Contains a brief overview of the field, end-of-chapter keywords for easy reference, and an extensive bibliography Physiologically Based Pharmacokinetic (PBPK) Modeling and Simulations: Principles, Methods, and Applications in the Pharmaceutical Industry, Second Edition is an indispensable single-volume resource for beginning and intermediate practitioners across the pharmaceutical sciences in both industry and academia.

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