Parexel Biopharmaceutical R D Statistical Sourcebook 2017

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Contemporary Biostatistics with Biopharmaceutical Applications CRC Press
Quantitative Methodologies and Process for Safety Monitoring and Ongoing Benefit Risk Evaluation provides a comprehensive coverage on safety monitoring methodologies, covering both global trends and regional initiatives. Pharmacovigilance has traditionally focused on the handling of individual adverse event reports however recently there had been a shift towards aggregate analysis to better understand the scope of product risks. Written to be accessible not only to statisticians but also to safety scientists with a quantitative interest, this book aims to bridge the gap in knowledge between medical and statistical fields creating a truly multi-disciplinary approach that is very much needed for 21st century safety evaluation.
Stem Cells in Regenerative Medicine CRC Press
This book provides an up-to-date monograph on the drug discovery and regulatory elements of therapeutics used to treat rare or "orphan" diseases.
2013-2014 Springer Science & Business Media
Drug discovery increasingly requires a common understanding by researchers of the many and diverse factors that go into the making of new medicines. The scientist entering the field will immediately face important issues for which his education may not have prepared him: project teams, patent law, consultants, target product profiles, industry trends, Gantt charts, target validation, pharmacokinetics, proteomics, phenotype assays, biomarkers, and many other unfamiliar topics for which a basic understanding must somehow be obtained. Even the more experienced scientist can find it frustratingly difficult to get an overview of the many factors involved in modern drug discovery and often only after years of exploring does a whole and integrated picture emerge in the mind of the researcher. Real World Drug Discovery: A Chemist’s Guide to Biotech and Pharmaceutical Research presents this kind of map of the landscape of drug discovery. In a single, readable volume it outlines processes and explains essential concepts and terms for the recent science graduate wondering what to expect in pharma or biotech, the medicinal chemist seeking a broader and more timely understanding of the industry, or the contractor or collaborator whose understanding of the commercial drug discovery process could increase the value of his contribution to it. Interviews with well-known experts in many of the fields involved, giving insightful comments from authorities on many of the sub-disciplines important to cutting edge drug discovery. Helpful suggestions gleaned from years of experience in biotech and pharma, which represents a repository drug discovery "lore" not previously available in any book. "Periodic Table of Drugs" listing current top-selling drugs arranged by target and laid out so that structural similarities and differences are plain and clear. Extensive use of diagrams to illustrate concepts like biotech startup models, preteomic profiling for target identification, Gantt charts for project planning, etc.
Intelligent Decision Technologies 2019 Springer
Providing a general guide to statistical methods used in the pharmaceutical industry, and illustrating how to use S-PLUS to implement these methods, the book explains why S-PLUS is a useful software package and discusses the results and implications of each particular application. It is targeted at graduates in biostatistics, statisticians involved in the industry as research scientists, regulators, academics, and/or consultants who want to know more about how to use S-PLUS and learn about other sub-fields within the industry, as well as statisticians in other fields who want to know more about statistical applications in the pharmaceutical industry.
Adaptive Design Theory and Implementation Using SAS and R
Royal Society of Chemistry
Vast global resources are ploughed into the delivery of treatment interventions ranging from diet and lifestyle advice to complex surgery. In all cases, whatever the intervention, unless the recipient is engaged with the process and understands why the intervention has been offered and the part they play in its success, compliance is an issue. Even where the individual does engage and understand, he or she may choose not to comply. Non-compliance is estimated to cost the pharma industry US$70 billion per year. No figures exist for the cost to healthcare insurers and public health but non-compliance is undoubtedly one of the top five issues facing both drug developers and healthcare providers. During clinical trials, non-compliance undermines the accuracy of the data generated from the whole trial as well as particular aspects such as the efficacy of different dosages. This book explores the key factors which drive compliance and the part that healthcare professionals can play in improving this, with the key underlying goal of improving public health in its broadest sense.
Parexel's Bio/Pharmaceutical Ramp;D Statistical Sourcebook 2010/2011 Barnett International, LLC
PAREXEL's Bio/Pharmaceutical R&D Statistical Sourcebook 2010/2011 is the leading resource for statistics, trends, and proprietary market intelligence and analysis on the biopharmaceutical industry. Supported by thousands of graphs, illustrations, and analysis, the Sourcebook provides the latest intelligence on every aspect of biopharmaceutical development - from product discovery, to R&D performance and productivity, to time-to-market trends.With key analysis and contributions from leading consultancies and experts, the sourcebook provides real-world data and analysis, including: * New proprietary analysis on US clinical trial starts, segmented by therapeutic category, as well as overall active clinical trials * Emerging data on worldwide and company-specific R&D pipelines and product launch trend * An all-new and comprehensive analysis of clinical research off-shoring revealing which pharma companies are now locating their new clinical trials overseas * New analysis on emerging trends in pharma and biotech licensing deals and other partnerships critical to industry's efforts * Drug approval statistics compiled from FDA, EMEA, and other regulatory agencies * New global R&D spending trends and other international R&D data from key markets * International statistics on drug development output * And much more! Plus, NEW in the 2010/2011 edition: * Analyses on the likely impact of theranostics * Analyses on personalized medicine and its impact on the biopharma market * Forecasting models on biopharma sales, R&D spending, and other meaningful industry metrics PAREXEL's Bio/Pharmaceutical R&D Statistical Sourcebook 2010/2011 is a must-have resource for the drug development industry. It is an invaluable resource for executives and managers working in the pharma and biotech industries. The Sourcebook puts real-world data sets at your fingertips for presentations, reports, business development efforts, strategic meetings, and critical decision-making analyses. The 2010/2011 edition will once again be offered in electronic format for individual users, small groups, business units, or for company-wide access.
Balancing Incentives for Innovation : Hearing Before the Subcommittee on Courts and Competition Policy of the Committee on the Judiciary, House of Representatives, One Hundred Eleventh Congress, First Session, July 14, 2009 John Wiley & Sons
A guide to making the drug-development process more efficient, by way of analyzing various steps in clinical research.
The Business, Legal, Regulatory and Tax Environment in the Pharmaceutical and Biotechnology Sectors PAREXEL Biopharmaceutical R & D Statistical Sourcebook, 2014/2015Parexel's Biopharmaceutical R & D Statistical Sourcebook 2012/2013
What’s the Deal with Biosimilars? Biosimilars are gaining momentum as new protein therapeutic candidates that can help fill a vital need in the healthcare industry. The biological drugs are produced by recombinant DNA technology that allows for large-scale production and an overall reduction time in costs and development. Part of a two-volume set that covers varying aspects of biosimilars, Biosimilars and Interchangeable Biologics: Strategic Elements explores the strategic planning side of biosimilar drugs and targets issues surrounding biosimilars that are linked to legal matters. This includes principal patents and intellectual property, regulatory pathways, and concerns about

affordability on a global scale. It addresses the complexity of biosimilar products, and it discusses the utilization of biosimilars and related biological drugs in expanding world markets. Of specific interest to practitioners, researchers, and scientists in the biopharmaceutical industry, this volume examines the science, technology, finance, legality, ethics, and politics of biosimilar drugs. It considers strategic planning elements that include an overall understanding of the history and the current status of the art and science of biosimilars, and it provides detailed descriptions of the legal, regulatory, and commercial characteristics. The book also presents a global strategy on how to build, take to market, and manage the next generation of biosimilars throughout their life cycle.

PAREXEL BIOPHARMACEUTICAL R&D STATISTICAL SOURCEBOOK. John Wiley & Sons

The book aims to provide both comprehensive reviews of the classical methods and an introduction to new developments in medical statistics. The topics range from meta analysis, clinical trial design, causal inference, personalized medicine to machine learning and next generation sequence analysis. Since the publication of the first edition, there have been tremendous advances in biostatistics and bioinformatics. The new edition tries to cover as many important emerging areas and reflect as much progress as possible. Many distinguished scholars, who greatly advanced their research areas in statistical methodology as well as practical applications, also have revised several chapters with relevant updates and written new ones from scratch.The new edition has been divided into four sections, including, Statistical Methods in Medicine and Epidemiology, Statistical Methods in Clinical Trials, Statistical Genetics, and General Methods. To reflect the rise of modern statistical genetics as one of the most fertile research areas since the publication of the first edition, the brand new section on Statistical Genetics includes entirely new chapters reflecting the state of the art in the field.Although tightly related, all the book chapters are self-contained and can be read independently. The book chapters intend to provide a convenient launch pad for readers interested in learning a specific topic, applying the related statistical methods in their scientific research and seeking the newest references for in-depth research.

Parexel Biopharmaceutical R & D Statistical Sourcebook John Wiley & Sons

Adaptive design has become an important tool in modern pharmaceutical research and development. Compared to a classic trial design with static features, an adaptive design allows for the modification of the characteristics of ongoing trials based on cumulative information. Adaptive designs increase the probability of success, reduce costs and the time to market, and promote accurate drug delivery to patients. Reflecting the state of the art in adaptive design approaches, Adaptive Design Theory and Implementation Using SAS and R provides a concise, unified presentation of adaptive design theories, uses SAS and R for the design and simulation of adaptive trials, and illustrates how to master different adaptive designs through real-world examples. The book focuses on simple two-stage adaptive designs with sample size re-estimation before moving on to explore more challenging designs and issues that include drop-loser, adaptive dose-funding, biomarker-adaptive, multiple-endpoint adaptive, response-adaptive randomization, and Bayesian adaptive designs. In many of the chapters, the author compares methods and provides practical examples of the designs, including those used in oncology, cardiovascular, and inflammation trials. Equipped with the knowledge of adaptive design presented in this book, you will be able to improve the efficiency of your trial design, thereby reducing the time and cost of drug development.

PAREXEL's Pharmaceutical R&D Statistical Sourcebook Neal Schuman Pub

With the most comprehensive and up-to-date overview of structure-based drug discovery and using experimental and computational approaches, this book covers principles, methods, applications, and emerging paradigms of structural biology as a tool for more efficient drug development. Presents the benefits, limitations, and potentiality of novel techniques in the field, like complex crystallization, X-ray diffraction, NMR, mass spectrometry, and computational chemistry Assesses macromolecular structures with experimental, analytical, and therapeutic approaches to reveal a successful, multidisciplinary perspective to drug development Includes detailed chapters on concepts, like protein dynamics, structure-based chemogenomics and polypharmacology, and fragment-based drug design Illustrates advances in biomolecular targeting using case studies and emerging examples: epigenetic proteins, HCV inhibitors, HIV-1 inhibitors, ribosomes, and antibodies

Proceedings of the 11th KES International Conference on Intelligent Decision Technologies (KES-IDT 2019), Volume 1 CRC Press

Leading economists discuss how economic policy can stimulate technological innovation.

New Scientist MIT Press

The field of contract research and manufacturing broadly encompasses those services in the pharmaceutical and biotechnology sectors that require extensive research and development and large-scale manufacturing facilities. The field has great potential for growth in the Indian outsourcing industry, which is world-renowned for its provision of cheap and highly-skilled services. Contract research and manufacturing services (CRAMS) in India provides a detailed account of the current scenario in India and the advantages that the Indian outsourcing industry can offer in the field of CRAMS. Following an overview of the services and their emergence in India, chapters in the book begin by discussing the legal and regulatory scenario and major concerns and issues. In the latter part of the book, topics covered include service agreements, dispute resolution and contract negotiations, followed by a discussion of the outlook for CRAMS in India and some concluding remarks. Several appendices are included, offering a list of major players in the field and various forms for use in licence applications. Simple and accessible presentation using tables, charts and diagrams Practical tips from leading practitioners Inclusion of relevant case laws and other legal considerations

PAREXEL Biopharmaceutical R & D Statistical Sourcebook, 2014/2015 Barnett International, LLC

The PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2012/2013 is the leading resource for statistics, trends, and proprietary market intelligence and analysis on the biopharmaceutical industry. Supported by thousands of graphs, illustrations, and analysis, the Sourcebook provides the latest market intelligence on every aspect of biopharmaceutical development – from product discovery, to R&D performance and productivity, to time-to-market trends. With key analysis and contributions from leading consultancies and experts, the Sourcebook provides real-world data and analysis, including: * A record number of all-new metrics on drug development costs and complexity. * New proprietary analyses on US clinical trial starts, segmented by therapeutic category, as well as overall active clinical trials. * Emerging data on worldwide and company-specific R&D pipelines, strategies, and product launch trends. * New analyses on emerging trends in pharma and biotech licensing deals and other partnerships critical to industry's efforts. * Drug approval statistics compiled from FDA, EMEA, and other regulatory agencies. * New global R&D spending trends and other international R&D data from key markets. * International statistics on drug development output. * And much more! Plus, NEW in the 2012/2013 edition: * An all-new 2012 analysis on the current share of clinical trial spending by region for 2011. * All-new studies on the emerging clinical trial markets in India, China, Korea, Canada, and dozens of other key markets and regions. * All-new analyses and actual/projected metrics on the biosimilars market. * A series of new "dashboards" on costs by phase of development, R&D attrition rates, product development times, and other areas. * Forecasting models on biopharma sales, R&D spending, the pharma/biotech markets, and other meaningful industry metrics. The PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2012/2013 is a must-have resource for the drug development industry. It is an invaluable resource for executives and managers working in the pharma and biotech industries. The Sourcebook puts real-world data sets at your fingertips for presentations, reports, business development efforts, strategic meetings, and critical decision-making analyses.

Trials and Errors in Clinical Research Elsevier

This is the long-awaited third edition of the most comprehensive compilation of drug information resources available. A co-publication with the Medical Library Association, it draws on industry expert Bonnie Snow's 30+ years of experience with pharmaceutical information needs and applications. Snow reviews 400+ print and electronic resources.More than a bibliography, this readable guide brings together the best resources plus practical advice on everything from expert search techniques to core collections for libraries. Subject areas covered include: pharmaceutical technology; legal and regulatory issues world-wide; industrial pharmacy; market research; product guides and prescribing information in the global marketplace; drug interactions; drug effects on pregnancy, lactation, and reproduction; pharmacovigilance; and much, much more. Completely revised, reorganized, and updated, the third edition focuses on information sources not covered elsewhere. Absolutely unique in its value as both a desk reference and a text for classroom use or self-study, this edition manages to meet the needs of students, information professionals, health care providers, and pharmacy practitioners.

Commercialization Secrets for Scientists and Engineers Edward Elgar Publishing

Since the publication of the first edition in 2000, there has been an explosive growth of literature in biopharmaceutical research and development of new medicines. This encyclopedia (1) provides a comprehensive and unified presentation of designs and analyses used at different stages of the drug development process, (2) gives a well-balanced summary of current regulatory requirements, and (3) describes recently developed statistical methods in the pharmaceutical sciences. Features of the Fourth Edition: 1. 78 new and revised entries have been added for a total of 308 chapters and a third volume has been added to encompass the increased number of chapters. 2. Revised and updated entries reflect changes and recent developments in regulatory requirements for the drug review/approval process and statistical designs and methodologies. 3. Additional topics include multiple-stage adaptive trial design in clinical research, translational medicine, design and analysis of biosimilar drug development, big data analytics, and real world evidence for clinical research and development. 4. A table of contents organized by stages of biopharmaceutical development provides easy access to relevant topics. About the Editor: Shein-Chung Chow, Ph.D. is currently an Associate Director, Office of Biostatistics, U.S. Food and Drug Administration (FDA). Dr. Chow is an Adjunct Professor at Duke University School of Medicine, as well as Adjunct Professor at Duke-NUS, Singapore and North Carolina State University. Dr. Chow is the Editor-in-Chief of the Journal of Biopharmaceutical Statistics and the Chapman & Hall/CRC Biostatistics Book Series and the author of 28 books and over 300 methodology papers. He was elected Fellow of the American Statistical Association in 1995.

Advanced Medical Statistics (2nd Edition) Elsevier

This edited volume presents current research in biostatistics with emphasis on biopharmaceutical applications. Featuring contributions presented at the 2017 ICSA Applied Statistics Symposium held in Chicago, IL on June 25 to 28, 2017, this book explores timely topics that have a high potential impact on statistical methodology and future research in biostatistics and biopharmaceuticals. The theme of this conference was Statistics for a New Generation: Challenges and Opportunities, in recognition of the advent of a new generation of statisticians. The conference attracted statisticians working in academia, government, and industry; domestic and international statisticians. From the conference, the editors selected 28 high-quality presentations and invited the speakers to prepare full chapters for this book. These contributions are divided into four parts: Part I Biostatistical Methodology, Part II Statistical Genetics and Bioinformatics, Part III Regulatory Statistics, and Part IV Biopharmaceutical Research and Applications. Featuring contributions on topics such as statistics in genetics, bioinformatics, biostatistical methodology, and statistical computing, this book is beneficial to researchers, academics, practitioners and policy makers in biostatistics and biopharmaceuticals.

Practical and Cross-Disciplinary Approaches World Scientific

A real-world guide to the production and manufacturing of biopharmaceuticals While much has been written about the science of biopharmaceuticals, there is a need for practical, up-to-date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products. This book helps fill the gap in the field, examining all areas of biopharmaceuticals manufacturing, from development and formulation to production and packaging. Written by a group of experts from industry and academia, the book focuses on real-world methods for maintaining product integrity throughout the commercialization process, clearly explaining the fundamentals and essential pathways for all development stages. Coverage includes: Research and early development phase–appropriate approaches for ensuring product stability Development of commercially viable formulations for liquid and lyophilized dosage forms Optimal storage, packaging, and shipping methods Case studies relating to therapeutic monoclonal antibodies, recombinant proteins, and plasma fractions Useful analysis of successful and failed products Formulation and Process Development Strategies for Manufacturing Biopharma-ceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries, for government and regulatory agencies, and for anyone with an interest in the latest developments in the field.

Orphan Drugs and Rare Diseases Pearson Education

PAREXEL Biopharmaceutical R & D Statistical Sourcebook, 2014/2015Parexel's Biopharmaceutical R & D Statistical Sourcebook 2012/2013Barnett International, LLC

PAREXEL Biopharmaceutical Ramp;D Statistical Sourcebook 2011/2012 CRC Press

The processes of discovery, testing and distribution of new medicines have undergone radical change in recent decades, from a focus on small molecule drugs to biomedicine and related technologies. Bruce Rasmussen very effectively draws upon modern theories of the firm, data analysis, and case studies to provide important insights into the consequences of this change. He offers convincing evidence that contradicts the widely-held view that the biopharmaceutical sector has not generated considerable economic value. Frank R. Lichtenberg, Columbia University, US Bio- and pharmaceutical industry discovery is a distressed asset today. Why? Bruce Rasmussen s book is a timely and very informative work, building on rich data sources and extensive economic research, on a subject of concern to us all. Is medicine discovery in permanent decline? Are the biotechnology and traditional pharma groups on a collision course, will the traditional group absorb the new, will integration take place, will a new discovery model emerge? I commend Bruce s book to all who wish to understand what is happening. David W. Anstice, Merck & Co., Inc. This path-breaking book addresses the ongoing implications for traditional pharmaceutical companies and biopharmaceutical start-ups of the realignment of the industry knowledge-base. The theoretical approach draws on the modern

theory of the firm and related ideas in order to better define the concept of the business model, which is employed to guide the case studies and empirical analysis in the book. The author shows that while traditional pharmaceutical companies have successfully adjusted their business models to meet the challenges of biotechnology, biopharmaceutical start-ups have experienced more problems. Despite the poor financial performance of the vast majority of these firms, the biopharmaceutical sector as a whole has created significant value. However, this has been captured disproportionately by a handful of large, fully-integrated biopharmaceutical firms and, to a lesser extent, by the largest dozen pharmaceutical companies. This highly focused book will be a captivating read for innovation and biopharmaceutical industry analysts, as well as advisers formulating policies to support the development of the biopharmaceutical sector. Academics working on innovation and biotechnology, as well as scientists engaged in research in the life sciences, will also find this book of particular interest.