Parexel Biopharmaceutical R D Statistical Sourcebook 2017

A guide to making the drug-development process more efficient, by way of analyzing various steps in clinical research.

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.

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.

Incentives for innovation are particularly relevant in the pharmaceutical industry where not all social needs provide equally profitable opportunities and where most OECD countries try to implement different measures that promote research in these less profitable areas. This book describes how incentives can be provided to deal with less profitable activities when no clear markets exist for the innovations. The book discusses alternative mechanisms to substitute for inexistent markets, situations where traditional instruments have proven totally insufficient, and the clear mismatch between the size of the markets being targeted and the incentives being provided. Patents become an ineffective way to incentivise R&D when the appropriability is low; this book provides alternative ideas such as allowing for a period of data exclusivity to firms that develop new drugs.

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.

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.

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.

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.

This book provides an up-to-date monograph on the drug discovery and regulatory elements of therapeutics used to treat rare or "orphan" diseases.

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

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.

Plunkett's Biotech & Genetics Industry Almanac 2007 is a complete reference guide to the business side of biotechnology, genetics, proteomics and related services. This new book contains complete profiles of the leading biotech companies, in-depth chapters on trends in genetics, technologies, statistics and finances, a handy glossary and thorough indexes. Plunkett's Biotech & Genetics Industry Almanac, our easy-to-understand reference to the biotech and genetics industry, is an absolutely vital addition to your office. For the first time, in one carefully-researched volume, you'll get all of the data you need. Topics include: A Short History of Biotechnology; The State of the Biotechnology Industry Today; Biotechnology funding and investments; Patents; Biotech activities in Singapore and China; FDA; Gene Therapies; Personalized Medicine; Systems Biology; Drug Development; Clinical Trials; Controversy over Drug Prices; Stem Cells Research; Therapeutic Cloning; Regenerative Medicine Nanotechnology; Agricultural Biotechnology; Drug Delivery Systems; BioShield; Ethical Issues. The book also includes complete profiles on over 400 Biotech & Genetics companies, our own unique list of companies that are the leaders in biotechnology. These are the largest, most successful corporations in all facets of this exploding business. All of the corporate profile information is indexed and cross-indexed, including contact names, addresses, Internet addresses, fax numbers, toll-free numbers, plus

growth and hiring plans, finances, research, marketing, technology, acquisitions and much more for each firm. Purchasers of either the book or PDF version can request a free copy of the company profiles database on CD-ROM, enabling export of contact names, addresses and more.

This book provides an overview of the theories and applications on subgroups in the biopharmaceutical industry. Drawing from a range of expert perspectives in academia and industry, this collection offers an overarching dialogue about recent advances in biopharmaceutical applications, novel statistical and methodological developments, and potential future directions. The volume covers topics in subgroups in clinical trial design; subgroup identification and personalized medicine; and general issues in subgroup analyses, including regulatory ones. Included chapters present current methods, theories, and case applications in the diverse field of subgroup application and analysis. Offering timely perspectives from a range of authoritative sources, the volume is designed to have wide appeal to professionals in the pharmaceutical industry and to graduate students and researchers in academe and government.

The global center of gravity in life sciences innovation is rapidly shifting to emerging economies. In The New Players in Life Science Innovation, Tomasz Mroczkowski explains how China and other new economic powers are rapidly gaining leadership positions, and thoroughly assesses the implications. Mroczkowski discusses the sophisticated innovation strategies and reforms these nations have implemented: approaches that don't rely on market forces alone, and are achieving remarkable success. Next, he previews the emerging global "bio-economy," in which life science discoveries will be applied pervasively in markets ranging from health to fuels. As R&D in the West becomes increasingly costly, Mroczkowski introduces new options for partnering with new players in the field. He thoroughly covers the globalization of clinical trials, showing how it offers opportunities that go far beyond cost reduction, and assessing the unique challenges it presents. Offering examples from China to Dubai to India, he carefully assesses the business models driving today's newest centers of innovation. Readers will find up-to-date coverage of bioparks, technology zones, and emerging clusters, and realistic assessments of global R&D collaboration strategies such as those of Eli Lilly, Merck, Novartis, and IBM. With innovation-driven industries increasingly dominating the global economy, this book's insights are indispensable for every R&D decision-maker and investor.

This book focuses on how to appropriately plan and develop a Phase II program, and how to design Phase II clinical trials and analyze their data. It provides a comprehensive overview of the entire drug development process and highlights key questions that need to be addressed for the successful execution of Phase II, so as to increase its success in Phase III and for drug approval. Lastly it warns project team members of the common potential pitfalls and offers tips on how to avoid them.

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.

This book is a unique guide to emerging stem cell technologies and the opportunities for their commercialisation. It provides in-depth analyses of the science, business, legal, and financing fundamentals of stem cell technologies, offering a holistic assessment of this emerging and dynamic segment of the field of regenerative medicine. • Reviews the very latest advances in the technology and business of stem cells used for therapy, research, and diagnostics • Identifies key challenges to the commercialisation of stem cell technology and avenues to overcome problems in the pipeline • Written by an expert team with extensive experience in the business, basic and applied science of stem cell research This comprehensive volume is essential reading for researchers in cell biology, biotechnology, regenerative medicine, and tissue engineering, including scientists and professionals, looking to enter commercial biotechnology fields.

Health care costs represent a nearly 18% of U.S. gross domestic product and 20% of government spending. While there is detailed information on where these health care dollars are spent, there is much less evidence on how this spending affects health. The research in Measuring and Modeling Health Care Costs seeks to connect our knowledge of expenditures with what we are able to measure of results, probing questions of methodology, changes in the pharmaceutical industry, and the shifting landscape of physician practice. The research in this volume investigates, for example, obesity’s effect on health care spending, the effect of generic pharmaceutical releases on the market, and the disparity between disease-based and population-based spending measures. This vast and varied volume applies a range of economic tools to the analysis of health care and health outcomes. Practical and descriptive, this new volume in the Studies in Income and Wealth series is full of insights relevant to health policy students and specialists alike.

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New Scientist magazine was launched in 1956 "for all those men and women who are interested in scientific discovery, and in its industrial, commercial and social consequences". The brand's mission is no different today - for its consumers, New Scientist reports, explores and interprets the results of human endeavour set in the context of society and culture.

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.

The book presents a collection of peer-reviewed articles from the 11th KES International Conference on Intelligent Decision Technologies (KES-IDT-19), held Malta on 17–19 June 2019. The conference provided opportunities for the presentation of new research results and discussion about them. It was also an opportunity to generation of new ideas in the field of intelligent decision making. The range of topics explored is wide, and covers methods of classification, prediction, data analysis, decision support, modelling and many more in such areas as finance, cybersecurity, economy, health, management and transportation. The topics cover also problems of data science, signal processing and knowledge engineering.

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

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For more than a decade, there has been widespread & increasing concern that the ability of the U.S. to achieve sustained economic growth & long-term prosperity is adversely affected by declining industrial competitiveness. This report on the U.S. biotechnology industry examines the structure of the industry & the current & emerging markets for biotechnology products. It discusses the factors likely to be critical in determining the future competitiveness of the industry: technology infrastructure & Fed. res. initiatives, capital formation, the U.S. health care system, tax policies, the regulatory environment, foreign competitors, & trade issues.

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.

Written with practitioners in mind, this new edition of Stephen’s Detection of Adverse Drug Reactions: Principle and Practice continues to be one of the corner stones of the pharmaceutical medicine list. The classic text covers the issues and problems involved in the detection of adverse drug reactions (ADRs) throughout the life cycle of a medicine from animal studies through to clinical trials, its introduction to the market, followed by wide clinical use, and eventual decline in use or withdrawal. The sixth edition is completely revised and updated including five new chapters on pharmacogenomics, ADRs with herbal medicines, safety of medical devices, safety issues with oncology drugs, and economic aspects of ADRs. All tables and web information needed in order to practice are included to make this sixth edition a

complete primer for the new practitioner and a reference for the more experienced.