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Optimization of Pharmaceutical R&D Programs and Portfolios
Constitution 3.0
Criminal justice analysis
The Gift of Participation
Commercial Health and Accident Insurance Industry
Promotional Strategies and New Service Opportunities in Emerging Economies
Practical Approaches to Risk Minimisation for Medicinal Products
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Monitoring and Evaluation of Climate Change Adaptation: A Review of the Landscape
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Harrison dates to 1891, during the exciting days of the Northwest's expansion. The area's forests were full of old growth pine, fir, and cedar. Lakes and rivers provided transportation. Logging camps, sawmills, homesteads, and towns were springing up. Harrison was such a town, growing from a squatter homestead to a bustling city of 2,000 with stores, hotels, saloons, and churches in 12 short years. Mills lined the waterfront vying for space with the railroad and steamship docks. The boom did not last, but its legacy is a small, proud, picturesque city on the shore of beautiful Lake Coeur

d'Alene.

His Brother's Keeper IGI Global

Very little has been published on optimization of pharmaceutical portfolios. Moreover, most of published literature is coming from the commercial side, where probability of technical success (PoS) is treated as fixed, and not as a consequence of development strategy or design. In this book there is a strong focus on impact of study design on PoS and ultimately on the value of portfolio. Design options that are discussed in different chapters are dose-selection strategies, adaptive design and enrichment. Some development strategies that are discussed are indication sequencing, optimal number of programs and optimal decision criteria. This book includes chapters written by authors with very broad backgrounds including financial, clinical, statistical, decision sciences, commercial and regulatory. Many authors have long held executive positions and have been involved with decision making at a product or at a portfolio level. As such, it is expected that this book will attract a very broad audience, including decision makers in pharmaceutical R&D, commercial and financial departments. The intended audience also includes portfolio planners and managers, statisticians, decision scientists and clinicians. Early chapters describe approaches to portfolio optimization from big Pharma and Venture Capital standpoints. They have stronger focus on finances and processes. Later chapters present selected statistical and decision analysis methods for optimizing drug development programs and portfolios. Some methodological chapters are technical; however, with a few exceptions they require a relatively basic knowledge of statistics by a reader.

Introductory Statistics ; a Decision Map Springer

The third edition of this title features contributions by leading experts on the important aspects of directors' liability, the protection available to directors and the risks of doing business in multiple jurisdictions. Each chapter includes commentary on civil claims and indemnification, regulatory and criminal liability, regulatory issues surrounding global D&O programmes and their ability to provide cover in all intended jurisdictions. The book is a powerful tool in assisting directors, officers, in-house counsel and the private practice lawyers advising them to make well-informed judgements about the risks they are taking.

You Might Be from Hamilton If... John Wiley & Sons

The Hammer. The Ambitious City. Steel town. Canada's tenth largest city, Hamilton, Ontario, has been called a lot of things. But Hamiltonians, near and far, know they can always come home to a place that has a rich history--and a lot of amusing stories only locals would know. In comes Graeme MacKay, the editorial cartoonist for the Hamilton Spectator. As a Hamiltonian born and bred, he knows this city's quirks, its characters and its love affair with being the underdog to Toronto's "Centre of the Universe" mentality. With more than 120 cartoons, MacKay illustrates what so many people have come to love (and perhaps cringe a little) about this port city. Founding father, George Hamilton, would be proud.

Insurance Law and Policy Springer Science & Business Media

In this “heartrending, passionate, and surprisingly humorous account of the conjunction between art and death” (Andrew Solomon, New York Times bestselling author), acclaimed opera singer Charity Tillemann-Dick recounts her remarkable journey from struggling to draw a single breath to singing at the most prestigious venues in the world after receiving not one but two double lung transplants. Charity Tillemann-Dick was a vivacious young American soprano studying at the celebrated Franz Liszt Academy of Music in Budapest when she received devastating news: her lungs were failing, her heart was three and a half sizes too big, and she would die within five years. Medical experts advised Charity to abandon her musical dreams, but if her time was running out, she wanted to spend it doing what she loved. In just three years, she endured two double lung transplants and had to slowly learn to breathe, walk, talk, eat, and sing again. With new lungs and fierce determination, she eventually fell in love, rebuilt her career, and reclaimed her life. More than a decade after her diagnosis, she has a chart-topping album, performs around the globe, and is a leading voice for organ donation. Weaving Charity’s extraordinary tale of triumph with those of opera’s greatest heroines, The Encore illuminates the indomitable human spirit and is “an uplifting story of overcoming significant odds to fulfill a dream” (Kirkus Reviews).

PRINCIPLES OF PRIVATE LAW Springer

This book proposes and investigates a universal framework, and accompanying documentation system, to facilitate and catalogue benefit-risk decisions; a valuable addition to the benefit-risk toolbox. Over the past decade, pharmaceutical companies and regulatory agencies have been reviewing the benefit-risk assessment of medicines with a view to developing a structured, systematic, standardized approach. Examining the evaluation of such an approach by several mature regulatory authorities ensures that the reader gains a unique insight into the ongoing debate in this area. The field of benefit-risk assessment continues to evolve at a rapid pace due to political and societal pressure, as is reflected in the recent FDA PUDFA agreement as well as in the EMA 2015 Roadmap. Rather than provide a comprehensive snap-shot of this constantly changing environment, this book evaluates selected current approaches to benefit-risk assessment. The strengths and weaknesses of publicly available documents in communicating benefit-risk decisions to stakeholders are reviewed and these evaluations are used to inform development of a prospective framework that could be used to harmonise procedures globally.

The Cost of Prescription Drugs Jones & Bartlett Learning

Monitoring and evaluation (M&E) of climate change adaptation (CCA) poses an assortment of thorny methodological challenges. Individually, none are unique to CCA, but together they represent a very distinctive conundrum facing practitioners and policy makers. Adding to this complexity further, climate change may be global in nature but its impacts, and how we respond to them through adaptation efforts, cut across scales, sectors, and levels of intervention. As investments in climate adaptation increase, organizations are seeking to measure, assess and understand an array of adaptation initiatives, and derive learnings to inform policy and praxis. This issue presents findings from many of the most important contemporary CCA program evaluation research initiatives. The chapters represent the most coherent and current collection of CCA M&E research in this emerging and important field, written by many of its leading experts. Filled with examples and insights in formulating coherent responses to methodological challenges, it will be of interest to M&E scholars and practitioners globally. This is the 147th issue in the New Directions for Evaluation series from Jossey-Bass. It is an official publication of the American Evaluation Association.

Optimization of Pharmaceutical R&D Programs and Portfolios Nova Snova

Comparative effectiveness research (CER) is the generation and synthesis of evidence that

compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care (IOM 2009). CER is conducted to develop evidence that will aid patients, clinicians, purchasers, and health policy makers in making informed decisions at both the individual and population levels. CER encompasses a very broad range of types of studies—experimental, observational, prospective, retrospective, and research synthesis. This volume covers the main areas of quantitative methodology for the design and analysis of CER studies. The volume has four major sections—causal inference; clinical trials; research synthesis; and specialized topics. The audience includes CER methodologists, quantitative-trained researchers interested in CER, and graduate students in statistics, epidemiology, and health services and outcomes research. The book assumes a masters-level course in regression analysis and familiarity with clinical research.

Constitution 3.0 CISCRP

This edition includes both updates and new uses and issues concerning CTS, along with case studies of how clinical trial simulations are being applied in various therapeutic and application areas. Importantly, the book expands on the utility of CTS for informing decisions during drug development and regulatory review. Each chapter author was selected on the basis of demonstrated expertise in state-of-the-art application of CTS. The target audience for this volume includes researchers and scientists who wish to consider use of simulations in the design, analysis, or regulatory review and guidance of clinical trials. This book does not embrace all aspects of trial design, nor is it intended as a complete recipe for using computers to design trials. Rather, it is an information source that enables the reader to gain understanding of essential background and knowledge for practical applications of simulation for clinical trial design and analysis. It is assumed that the reader has a working understanding of pharmacokinetics and pharmacodynamics, modeling, pharmacometric analyses, and/or the drug development and regulatory processes.

Criminal justice analysis Drug Safety Data

Drug Safety DataJones & Bartlett Learning

The Gift of Participation HarperCollins UK

Risk management of medicines is a wide and rapidly evolving concept and practice, following a medicine throughout its lifecycle, from first administration in humans through clinical studies and then marketing in the patient population at large. Previous reports from CIOMS I - VIII provided practical guidance in some essential components of risk management such as terminology and reporting of adverse drug reactions, management of safety information from clinical trials, and safety signal detection. Beyond the detection, identification, and characterization of risk, "risk minimization" is used as an umbrella term for the prevention or mitigation of an undesirable outcome. Risk management always includes tools for "routine risk minimization" such as product information, the format depending on the jurisdiction, to inform the patient and the prescriber, all of which serve to prevent or mitigate adverse effects. Until this current CIOMS IX document, limited guidance has been available on how to determine which risks need "additional risk minimization," select the appropriate tools, apply and implement such tools globally and locally, and measure if they are effective and valuable. Included in the report is a CIOMS framework for the evaluation of effectiveness of risk minimization, a discussion of future trends and developments, an annex specifically addressing vaccines, and examples from real life.

Commercial Health and Accident Insurance Industry CRC Press

At the beginning of the twenty-first century, breathtaking changes in technology are posing stark challenges to our constitutional values. From free speech to privacy, from liberty and personal autonomy to the right against self-incrimination, basic constitutional principles are under stress from technological advances unimaginable even a few decades ago, let alone during the founding era. In this provocative collection, America's leading scholars of technology, law, and ethics imagine how to translate and preserve constitutional and legal values at a time of dizzying technological change. Constitution 3.0 explores some of the most urgent constitutional questions of the near future. Will privacy become obsolete, for example, in a world where ubiquitous surveillance is becoming the norm? Imagine that Facebook and Google post live feeds from public and private surveillance cameras, allowing 24/7 tracking of any citizen in the world. How can we protect free speech now that Facebook and Google have more power than any king, president, or Supreme Court justice to decide who can speak and who can be heard? How will advanced brain-scan technology affect the constitutional right against self-incrimination? And on a more elemental level, should people have the right to manipulate their genes and design their own babies? Should we be allowed to patent new forms of life that seem virtually human? The constitutional challenges posed by technological progress are wide-ranging, with potential impacts on nearly every aspect of life in America and around the world. The authors include Jamie Boyle, Duke Law School; Eric Cohen and Robert George, Princeton University; Jack Goldsmith, Harvard Law School; Orin Kerr, George Washington University Law School; Lawrence Lessig, Harvard Law School; Stephen Morse, University of Pennsylvania Law School; John Robertson, University of Texas Law School; Christopher Slobogin, Vanderbilt Law School; O. Carter Snead, Notre Dame Law School; Jeffrey Rosen, George Washington University Law School; Benjamin Wittes, Brookings Institution; Tim Wu, Columbia Law School; and Jonathan Zittrain, Harvard Law School.

Promotional Strategies and New Service Opportunities in Emerging Economies Arcadia Publishing

Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk was selected for The First Clinical Research Bookshelf - Essential reading for clinical research professionals by the Journal of Clinical Research Best Practices. Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk provides drug safety/pharmacovogilance professionals, pharmaceutical and clinical research scientists, statisticians, programmers, medical writers, and technicians with an accessible, practical framework for the analysis, summary and interpretation of drug safety data. The only guide of its kind, Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk is an invaluable reference for pre- and post-marketing risk assessment. With decades of pharmaceutical research and drug safety expertise, authors Dr. Klepper and Dr. Cobert discuss how quality planning, safety training, and data standardization result in significant cost, time, and resource savings. Through illustrative, step-by-step instruction, Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk is the definitive guide to drug safety data analysis and reporting. Key features include: * Step-by-step instruction on how to analyze, summarize and interpret safety data for mandatory governmental safety reports * Pragmatic tips...and mistakes to avoid * Simple

explanations of what safety data are collected, and what the data mean * Practical approaches to determining a drug effect and understanding its clinical significance * Guidance for determining risk throughout the lifecycle of a drug, biologic or nutraceutical * Examples of user-friendly data displays that enhance safety signal identification * Ways to improve data quality and reduce the time, resources and costs involved in mandatory safety reporting * Relevant material for the required training of drug safety/pharmacovigilance professionals * SPECIAL FEATURE: Actual examples of an Integrated Analysis of Safety (IAS) -used in the preparation of the Integrated Summary of Safety (ISS) and the Summary of Clinical Safety (SCS) reports -, and the Periodic Safety Update Report (PSUR)

Practical Approaches to Risk Minimisation for Medicinal Products Simon and Schuster

Continuous improvements in emerging economies have created more opportunities for industrialization and rapid growth. This not only leads to higher standards in accounting and security regulations, but it increases the overall marketing efficiency. Promotional Strategies and New Service Opportunities in Emerging Economies is a key resource in the field of service marketing and promotions, service innovations, and branding in developing countries. Highlighting multidisciplinary studies on self-service technologies, sustainable consumption, and customer relation management, this publication is an ideal reference source for policy makers, academicians, practitioners, researchers, students, marketers, and government officials actively involved in the services industry.

Ginsberg & Martin on Bankruptcy Rowman & Littlefield

The prescription drug delivery systemâhow a drug gets from the manufacturer to the patientâis complicated. More than 4.4 billion prescriptions are written for drugs each year for Americans who then pick up these prescriptions at 60,000 drugstores or receive them from doctors or hospitals or online pharmacies. Chapter 1 is about how Americans pay for prescription drugs and where that money goes. Chapter 2 is about the process, beginning with the manufacturer's development of a drug, the different steps through which the drug travels before arriving in a patient's hands, how this is paid for, and what the costs are at each step along the way.

CRC Press

Arithmetic and algebra; Flow charts and decision maps; Graphing; Characteristics of a distribution; Transformations of scale; Theoretical distributions; Probability; Hypothesis testing; Comparing proportions or entire distributions; Comparing variances; Comparing means: one or two samples; Comparing means: three or more samples; Hypothesis tests with ordinal scales; Prediction; Correlation: pearson and related formulas; Other two-variable correlation indices; Correlating three or more variables.

Monitoring and Evaluation of Climate Change Adaptation: A Review of the Landscape Aspen Publishing

Pulitzer-prize winning author Jonathan Weiner's revealing story of the science that is about to change all life forever.Biology used to be a science of the way things are. Now it is a science of the way things work, like physics or engineering. Biology's progress fascinates and appals us because it has gone from learning the ways of nature to trying to turn her. In his extraordinary new book, Jonathan Weiner reveals the life-changing discoveries that have been converging over the past half a century to bring us to a moment when biology has the power to change life as we know it.When Stephen Heywood, a carpenter, discovered he had A.L.S., a gradual, mysterious deterioration of the nervous system, Jamie Heywood, gave up his lucrative job to try and save his brother's life. He worked with cutting-edge scientists in a race to find a cure. Through this remarkable journey with a family in crisis, we are given an overview of the various gene therapies that are still on the horizon, capable of potentially bringing back those suffering from neurological diseases such as ALS, Alzheimer's, Parkinson's, and other various disorders of the brain. Through Jonathan Weiner's translucent prose, we e

Methods in Comparative Effectiveness Research

A contemporary, easy-to-teach text by high-profile authors, this casebook invites students and teachers to re-imagine the field of Insurance Law. The authors demonstrates the big-picture role of insurance law and policy in American business and society, exploring federal-state regulatory roles in depth as well as the traditional topics covered in casebooks. Insurance Law and Policy: Cases and Materials uses more statutory material than any other casebook, with statutes typically presented through problems. Manageable assignments contain one major case followed by informative notes, questions and a problem.

Drug Safety Data

Kennth Getz takes a fresh look at why participation in clinical research really matters. This book addresses what clinical participation means and how it helps to advance medical science. Practical information on subjects like insurance coverage, compensation, and tax ramifications for clinical research volunteers also is included. With a foreword written by Congressman Rick Boucher of Virginia, and a back cover endorsement from Tour de France winner and cancer survivor Lance Armstrong, offers a road map into a world many readers are just beginning to explore.

The Pacific Northwest-Pacific Southwest Intertie

Offering an introduction to Cloud-based healthcare IT system, this timely book equips healthcare providers with the background necessary to evaluate and deploy Cloud-based solutions to today’s compliance and efficiency issues. Divided into three sections, it first discusses Cloud Service technologies and business models as well as the pros and cons of Cloud Services as compared to traditional in-house IT solutions. The second reviews applications in healthcare and a review of HIPAA and HITECH provisions. Finally, the book addresses the process of adopting Cloud solutions, including vendor evaluation, migration strategies, and managing transition risks. It concludes with a look at related topics and real-world case studies.

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