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ERICK ALVARO

Reliability and Validity of Data Sources for Outcomes Research & Disease and Health Management Programs MDPI
This is the first book to offer a comprehensive guide to involving patients in health technology assessment (HTA). Defining patient involvement as patient participation in the HTA process and research into patient aspects, this book includes detailed explanations of approaches to participation and research, as well as case studies. Patient Involvement in HTA enables researchers, postgraduate students, HTA professionals and experts in the HTA community to study these complementary ways of taking account of patients' knowledge, experiences, needs and preferences. Part I includes chapters discussing the ethical rationale, terminology, patient-based evidence, participation and patient input. Part II sets out methodology including: Qualitative Evidence Synthesis, Discrete Choice Experiments, Analytical Hierarchy Processes, Ethnographic Fieldwork, Deliberative Methods, Social Media Analysis, Patient-Reported Outcome Measures, patients as collaborative research partners and evaluation. Part III contains 15 case studies setting out current activities by HTA bodies on five continents, health technology developers and patient organisations. Each part includes discussion chapters from leading experts in patient involvement. A final chapter reflects on the need to clearly define the goals for patient involvement within the context of the HTA to identify the optimal approach. With cohesive contributions from more than 80 authors from a variety of disciplines around the globe, it is hoped this book will serve as a catalyst for collaboration to further develop patient involvement to improve HTA. "If you're not involving patients, you're not doing HTA!" - Dr. Brian O'Rourke, President and CEO of CADTH, Chair of INAHTA
Technical Report Series World Health Organization
This report presents the recommendations of the WHO Expert Committee responsible for updating the WHO Model List of Essential Medicines. The first part contains a progress report on the new procedures for updating the Model List and the development of the WHO Essential Medicines Library. It continues with a section on changes made in revising the Model List followed by a review of some sections such as hypertensive medicines and fast track procedures for deleting items. Annexes include the 13th version of the Model List and items on the list sorted according to their 5-level Anatomical Therapeutic Chemical classification codes.
Dictionary for Clinical Trials Springer Nature
The Textbook of Pharmaceutical Medicine is a standardreference for all those working in pharmaceutical medicine and therecognised text for the UK Faculty of Pharmaceutical MedicineDiploma. This is a comprehensive volume covering the processes bywhich medicines are developed, tested and approved. Regulations fordrug development in the UK, EU, USA, Australia and Japan arediscussed, providing relevant information for drug approval in themain continents where new drugs are developed. The chapters are written by leading academics, medical directorsand lawyers, providing authoritative and in-depth information fortrainees on the Faculty course, and for physicians working in thepharmaceutical industry. As well as thorough updating of theregulatory chapters, the 6th edition includes chapters onthese vital new areas: Paediatric regulation Ethics Due diligence and the pharmaceutical physician
The Textbook of Pharmaceutical Medicine World Bank Publications
This book discusses the influence of the pharmaceutical industry on the practice of medicine, and the observed and potential pitfalls of such partnerships. It argues that the pharmaceutical industry has become indispensable to many of the activities of the medical profession across the pharmaceutical product lifecycle, and examines the regulatory, ethical, professional and institutional difficulties that arise from these interactions. With data drawn from over 80 qualitative accounts from medical, pharmaceutical, regulatory and healthcare professionals, this book uses both Hungary and the Netherlands as case studies to demonstrate the potential problem of undue pharmaceutical industry influence within the relationships fostered with the profession of medicine. Chapters systematically describe the lifecycle of a pharmaceutical product from research to distribution, demonstrating the interdependency of industry and medicine. Arguing that the medical profession should be a buffer between the pharmaceutical industry interests and patient interests, the book explores how undue industry influence weakens the ability of the medical profession to do so. Using the theory of institutional corruption, the book aims to analyze how conflict of interest and the weakening of institutional imperatives is a result of institutional interactions rather than individual actions. Appropriate for students and researchers of the pharmaceutical industry, corporate corruption, and those working in NGOs and policy making, this unique volume is an comprehensive look at the complex relationship between medicine and pharmacy.
Ethics Dumping Edward Elgar Publishing
In the European Union (EU), its Member States and the United Kingdom (UK) post-Brexit, as elsewhere, the marketing of pharmaceuticals is subject to an ever more complex web of legislation and regulation, resulting from the intense scrutiny necessary to ensure such essential products are not only

efficacious but also safe. This useful volume lays out this system with extraordinary clarity and logic. Adopting a Europe-wide perspective on the law governing pharmaceuticals, expert authors from the law firm Bird & Bird LLP map the life cycle of a medicinal product or medical device from development to clinical trials to product launch and ongoing pharmacovigilance, offering comprehensive and unambiguous guidance at every stage. Following a brief overview of how the exit from the EU by the UK currently affects the regulatory regime, as well as an introductory overview focusing on the regulatory framework for pharmaceuticals in Europe – from its underlying rationales to the relevant committees and agencies – each of the following twenty-one incisive chapters examines a particular process or subject. Among the many topics and issues covered from both an EU and UK perspective are the following: clinical trials; stages and standards for creating a product dossier; obtaining a marketing authorisation; how and when an abridged marketing authorisation procedure can be used; criteria for conditional marketing authorisations; generic products and 'essential similarity'; paediatric use and the requisite additional trials; orphan medicinal products; biologicals and 'biosimilars'; homeopathic, herbal and similar medicines; medical devices; pandemics, epidemics and vaccines; pharmacovigilance; parallel trade; advertising; and relevant competition law, intellectual property rights and data protection regulation. In addition, sample forms and URLs for the most important reference materials are included. Pharmaceutical lawyers and regulatory advisers, both in-house and in private practice, will welcome this unique book. It offers immeasurable value for all who need to understand the process of bringing a medicinal product or medical device to market and the continuing rights and obligations.

The Sedated Society World Health Organization

This edited volume provides an answer to a rising public health concern: what drives the over prescription of psychiatric medication epidemic? Over 15% of the UK public takes a psychiatric medication on any given day, and the numbers are only set to increase. Placing this figure alongside the emerging clinical and scientific data revealing their poor outcomes and the harms these medications often cause, their commercial success cannot be explained by their therapeutic efficacy.Chapters from an interdisciplinary team of global experts in critical psychopharmacology rigorously examine how pharmaceutical sponsorship and marketing, diagnostic inflation, the manipulation and burying of negative clinical trials, lax medication regulation, and neoliberal public health policies have all been implicated in ever-rising psycho-pharmaceutical consumption. This volume will ignite a long-overdue public debate. It will be of interest to professionals in the field of mental health and researchers ranging from sociology of health, to medical anthropology and the political economy of health.

The Many Faces of Corruption National Academies Press

Data sharing can accelerate new discoveries by avoiding duplicative trials, stimulating new ideas for research, and enabling the maximal scientific knowledge and benefits to be gained from the efforts of clinical trial participants and investigators. At the same time, sharing clinical trial data presents risks, burdens, and challenges. These include the need to protect the privacy and honor the consent of clinical trial participants; safeguard the legitimate economic interests of sponsors; and guard against invalid secondary analyses, which could undermine trust in clinical trials or otherwise harm public health. Sharing Clinical Trial Data presents activities and strategies for the responsible sharing of clinical trial data. With the goal of increasing scientific knowledge to lead to better therapies for patients, this book identifies guiding principles and makes recommendations to maximize the benefits and minimize risks. This report offers guidance on the types of clinical trial data available at different points in the process, the points in the process at which each type of data should be shared, methods for sharing data, what groups should have access to data, and future knowledge and infrastructure needs. Responsible sharing of clinical trial data will allow other investigators to replicate published findings and carry out additional analyses, strengthen the evidence base for regulatory and clinical decisions, and increase the scientific knowledge gained from investments by the funders of clinical trials. The recommendations of Sharing Clinical Trial Data will be useful both now and well into the future as improved sharing of data leads to a stronger evidence base for treatment. This book will be of interest to stakeholders across the spectrum of research-from funders, to researchers, to journals, to physicians, and ultimately, to patients.

House of Commons - Science and Technology Committee: Clinical Trials - HC 104 Cambridge University Press

In the US alone, pharmaceutical companies spend around $7 billion a year on clinical trials for drugs; all this in a global market where increasing competition and pressure on healthcare financing are both impacting on margins and profitability. One solution for pharmaceutical companies lies within the clinical trials themselves. If only you can communicate the trial findings to the right people, in the right way, you can benefit from this huge investment and add significant value to your product range and your brand. Successfully Marketing Clinical Trials Results is a comprehensive guide for every marketing professional faced with the challenge of using marketing to convert scientific data into sales. The book offers you practical knowledge on how to use medical research data to maximise the revenue from your products. There are sections explaining how to: identify your market and devise your strategy; develop your content and translate data into a message that has impact; use language, layout and illustrations to best effect; communicate internally as well as externally; make best use of the resources available; align your sales force and the external agencies with whom you work; lead the people in the project team; co-operate with the medical researchers, external experts and the press. In this book are answers for everything from how to handle class-effect questions to developing a shared brand vocabulary. There are plenty of vivid examples and real-life applications to reinforce the ideas. Cases studies illustrate solutions to problems; checklists and tips will help to implement the suggestions and recommendations. Günter Umbach has distilled the essence both of 25 years' experience in the healthcare market and of his highly successful seminar series on marketing clinical trials into the professional advice given in this book. The text is accompanied by a CD ROM containing detailed Powerpoint slides supporting e

The Internet of Things Springer Nature

This book constitutes the refereed proceedings of the 6th International Conference on Convergence and Hybrid Information Technology, ICHIT 2012, held in Daejeon, Korea, in August 2012. The 102 revised full papers presented were carefully reviewed and selected from 196 submissions. The papers are organized in topical sections on communications and networking; soft computing and intelligent systems; medical information and bioinformatics; security and safety systems; HCI and data mining;

software and hardware engineering; image processing and pattern recognition; robotics and RFID technologies; convergence in information technology; workshop on advanced smart convergence (IWASC).

Ethical Criteria for Medicinal Drug Promotion Oxford University Press

This book examines the important role of consumer activism in health policy in different national contexts. In an age of shifting boundaries between state and civil society, consumer groups are potentially drivers of democratisation in the health domain. The expert contributors explore how their activities bring new dynamics to relations between service providers, the medical profession, government agencies, and other policy actors. This book is unique in comprehensivelyanalysing the opportunities and dilemmas of this type of activism, including ambiguous partnerships between consumer groups and stakeholders such as the pharmaceutical industry. These themes are explored within aninternationally comparative framework, with case studies from various countries.

The Business of Healthcare Innovation Springer Nature

In Real-World Evidence in the Pharmaceutical Landscape, life science industry experts Sunil Dravida and his co-authors have developed the first comprehensive overview of its kind on Real-World Data (RWD) in the pharmaceutical industry. The authors examine the challenges and opportunities in applying real-world data along the pharmaceutical continuum, from clinical development to medical affairs, health economics and outcomes, and marketing. They address the difficulties identifying the suitable data sources, ensuring compliance with privacy, security and regulatory requirements, and the big job of translating data into Real-World Evidence (RWE) to generate meaningful insights that can improve decision making by stakeholders and measurable outcomes that can enhance people’s health and well-being. This book is a must-read for those in the pharmaceutical industry involved with RWD, which includes just about every role, as healthcare is now dominated by the need for high-quality data that can enable better decision-making. This book is especially critical for those designing and leading RWD Centers of Excellence in pharmaceutical companies and the service providers supporting the RWD ecosystem.

The Global Guide to Pharma Marketing Codes Springer Nature

The 3D printing (3DP) process was patented in 1986; however, only in the last decade has it begun to be used for medical applications, as well as in the fields of prosthetics, bio-fabrication, and pharmaceutical printing. 3DP or additive manufacturing (AM) is a family of technologies that implement layer-by-layer processes in order to fabricate physical models based on a computer aided design (CAD) model. 3D printing permits the fabrication of high degrees of complexity with great reproducibility in a fast and cost-effective fashion. 3DP technology offers a new paradigm for the direct manufacture of individual dosage forms and has the potential to allow for variations in size and geometry as well as control dose and release behavior. Furthermore, the low cost and ease of use of 3DP systems means that the possibility of manufacturing medicines and medical devices at the point of dispensing or at the point of use could become a reality. 3DP thus offers the perfect innovative manufacturing route to address the critical capability gap that hinders the widespread exploitation of personalized medicines for molecules that are currently not easy to deliver. This Special Issue will address new developments in the area of 3D printing and bioprinting for drug delivery applications, covering the recent advantages and future directions of additive manufacturing for pharmaceutical products.

Guide to EU Pharmaceutical Regulatory Law The Stationery Office

How has the regulation of business shifted from national to global institutions? What are the mechanisms of globalization? Who are the key actors? What of democratic sovereignty? In which cases has globalization been successfully resisted? These questions are confronted across an amazing sweep of the critical areas of business regulation--from contract, intellectual property and corporations law, to trade, telecommunications, labor standards, drugs, food, transport and environment. This book examines the role played by global institutions such as the World Trade Organization, World Health Organization, the OECD, IMF, Moodys and the World Bank, as well as various NGOs and significant individuals. Incorporating both history and analysis, Global Business Regulation will become the standard reference for readers in business, law, politics, and international relations.

Patient Involvement in Health Technology Assessment OECD Publishing

At any point in the drug development process, systematic reviews and meta-analysis can provide important information to guide the future path of the development program and any actions that might be needed in the post-marketing setting. This report gives the rationale for why and when a meta-analysis should be considered, all in the context of regulatory decision-making, and the tasks, data collection, and analyses that need to be carried out to inform those decisions. There is increasing demand by decision-makers in health care, the bio-pharmaceutical industry, and society at large to have access to the best available evidence on benefits and risks of medicinal products. The best strategy will take an overview of all the evidence and where it is possible and sensible, combine the evidence and summarize the results. For efficacy, the outcomes generally use the same or very similar predefined events for each of the trials to be included. Most regulatory guidance and many Cochrane Collaboration reviews have usually given more attention to assessment of benefits, while issues around combining evidence on harms have not been as well-covered. However, the (inevitably) unplanned nature of the data on safety makes the process more difficult. Combining evidence on adverse events (AEs), where these were not the focus of the original studies, is more challenging than combining evidence on pre-specified benefits. This focus on AEs represents the main contribution of the current CIOMS X report. The goal of the CIOMS X report is to provide principles on appropriate application of meta-analysis in assessing safety of pharmaceutical products to inform regulatory decision-making. This report is about meta-analysis in this narrow area, but the present report should also provide conceptually helpful points to consider for a wider range of applications, such as vaccines, medical devices, veterinary medicines or even products that are combinations of medicinal products and medical devices. Although some of the content of this report describes highly technical statistical concepts and methods (in particular Chapter 4), the ambition of the working group has been to make it comprehensible to non-statisticians for its use in clinical epidemiology and regulatory science. To that end, Chapters 3 and 4, which contain the main technical statistical aspects of the appropriate design, analysis and reporting of a meta-analysis of safety data are followed by Chapter 5 with a thought process for evaluating the findings of a meta-analysis and how to communicate these.

Essential Writing, Communication and Narrative Skills for Medical Scientists Before and After the COVID Era Zed Books
When the COVID- 19 pandemic occurred, all the main communication systems of medical research have undergone an epochal change. Many online journals and magazines have tried to publish inherent works of this specific problem as soon as possible, soliciting and preferring them to others, thus changing the system of free acceptance of scientific works once. Moreover, the way to communicate these works has no longer occurred through standard Scientific Congresses but with other systems, websites/streaming and webinars or virtual conferences. Now there is something systematic missing, which foresees that this may last in the future, in the post COVID-19 era (AC): the communication system of the medical sciences will be different from now on. There will be far fewer classical-style conferences like the ones so popular before COVID-19 outbreak (BC) but there will be more webinars, in streaming and virtual conferences. This new book fits well in this period, creating a bridge between those who do research, how it is communicated, what are the classic communication methods and what is all the necessary background to communicate with new tools. The book idea is based on the legacy left by Michael Faraday, the famous American chemist, who sensed how communicating what happens in science can make the difference between the success and failure of the research itself: “A lecturer should appear easy and collected, undaunted and unconcerned” “Lecturers which really teach will never be popular; lecturers which are popular will never really teach “ Michael Faraday, "Advice to lecturers", 1848 The volume approach is multidisciplinary and written by top experts in the field of communication and education. It will be a useful tool for scientists in this moment of epochal change in medical communication.
The Selection and Use of Essential Medicines Springer Nature
Representing the first book on the topic, this work offers the reader an introduction to the Japanese systems for health technology assessment (HTA) officially introduced by the Ministry of Health, Labour and Welfare (MHLW) in 2016. Policy and guidelines are discussed, with the relevant methods and conditions of cost-effectiveness analysis explained alongside. Numerous instructive examples and exercises, ranging from basic to advanced, impart valuable knowledge and insight on the quantitative methods for economic evaluation, which will appeal to both beginners and experts. This guidebook is authored by Japan’s foremost expert in HTA and pharmacoeconomics, with a view to strengthening the reader’s expertise in value-based healthcare and decision-making. The methods presented are essential to informing regulatory, local and patient decisions; as such, the book is equally recommended to industry and government, as well as academia, and anyone with an interest in Japanese HTA.
Institutional Corruption Theory in Pharmaceutical Industry-Medicine Relationships Kluwer Law International B.V.
Many of the trials taking place today are unregistered and unpublished, meaning that the information that they generate remains invisible to both the scientific community and the public. This undermines public trust, slowing the pace of medical advancement and potentially putting patients at risk. All trials conducted on NHS treatments-and all other trials receiving public funding-should be prospectively registered and their results published in a scientific journal. While the focus should be on implementing this change for future trials, the Government must also do what it can to ensure that historic trials are registered and published, particularly where they have been publically funded. The Government should also take steps to facilitate greater sharing of the raw data generated during a trial in a responsible and controlled way, with the knowledge and consent of patients. The report also draws attention to the recent fall in the number of trials taking place in the UK. It finds that the need for multiple governance approvals from participating NHS organisations remained the biggest barrier to setting up a UK trial, but that lack of public awareness was also a key issue. Recruiting participants can also be a challenge. The report calls on the Government to take its recommendations into account in ongoing discussions regarding the revision of European clinical trials legislation and in its response to the European Medicines Agency's consultation on the release of clinical trial data, which closes at the end of this month
Evidence Synthesis and Meta-analysis for Drug Safety Cambridge University Press
"This World Health Report was produced under the overall direction of Carissa Etienne ... and Anarfi Asamoa Baah ... The principal writers were David B. Evans ... [et al] -- t.p. verso.
Pharmaceutical Ethics Lulu.com
As a result of the expansion in the area of pharmaceutical medicine there is an ever-increasing need for educational resources. The Dictionary of Clinical Trials, Second Edition comprehensively explains the 3000 words and short phrases commonly used when designing, running, analysing and reporting clinical trials. This book is a quick, pocket reference tool to understand the common and less well-used terms within the discipline of clinical trials, and provides an alternative to the textbooks available. Terms are heavily cross-referenced, which helps the reader to understand how terms fit into the broad picture of clinical trials. Wide ranging, brief, pragmatic explanations of clinical trial terminology Scope includes medical, statistical, epidemiological, ethical, regulatory and data management terminology Thoroughly revised and expanded - increase of 280 terms from First Edition, reference to Cochrane included From the reviews of the First Edition: "This invaluable text explains the majority of clinical trial terms, in alphabetical order, that are likely to be found in clinical trial protocols, reports, regulatory guidelines, and published manuscripts... Fully comprehensive - provides definitions of clinical trial terms in one complete volume... Includes extensive use of graphs throughout." LA DOC STI "...covers a range of subject matter, with emphasis on medical, statistical, epidemiological and ethical terms... a useful adjunct to standard clinical trial texts... a reference source to keep within easy reach." TALANTA The Dictionary of Clinical Trials, Second Edition is a ‘must-have’ for all pharmaceutical companies who conduct a lot of clinical trials, in all or one therapeutic area. The book is also of interest for public health and health science workers, and for contract research organisations and departments of medicine, where medics are involved with clinical trials.
Successfully Marketing Clinical Trial Results John Wiley & Sons
This report assesses how pharmaceutical pricing and reimbursement policies have contributed to the achievement of certain health policy objectives, and it examines the national and transnational effects of these policies.