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AVA GEORGE

Confronting Corruption Springer-Verlag
Now in its fourth edition, Fraud and Misconduct in Biomedical Research boasts an impressive list of contributors from around the globe and introduces a new focus for the book, transforming it from a series of monographs into a publication that will quickly become an essential textbook on all areas of research fraud and misconduct.Key features inclu
Institutional Corruption Theory in Pharmaceutical Industry-Medicine Relationships Springer Science & Business Media
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
Tödliche Medizin und organisierte Kriminalität Igel Verlag RWS
In this textbook we examine the extent to which moral values play a role as productive forces for companies and the economy as a whole, and explores the effect of ethical and unethical behavior at both levels. We show how ethics improves productivity, and provide specific ethics tools for practical application for both students and managers. Stemming from an overall interdisciplinary approach, this textbook fills a gap in the literature on ethics in business. Following a textbook structure, we first derive knowledge from scientific studies that are relevant for students, and then summarize the results. We explain ethical assessment approaches, and then provide an ethical assessment of economic behavior using case studies. Roleplaying and games are used to explain the behavior of people in relation to ethics. The 2nd edition has been completely revised and expanded to include new findings from the behavioral sciences (psychology, social psychology, sociology and behavioral economics). In particular, the research on emotions, motivation and group behavior have given rise to many new impulses in business ethics. In addition, new case studies and new chapters were included, like Politics and Morality, Theories of Justice, Global Ethics, and Institutions as Solutions to Specific Game Situations (game theory). This book is important for students and researchers as well as policymakers and business executives due to its focus on applications.
Integrity of Scientific Research John Wiley & Sons
Das vorliegende Handbuch liefert einen konzisen Überblick und eine verlässliche Orientierungshilfe bei ethischen und rechtlichen Entscheidungsprozessen in der Forschung am Menschen. Es dient dabei einerseits als eine Dokumentation des Status quo, andererseits aber auch als Diskussionsgrundlage für zukünftige Entwicklungen. An dem Handbuch haben Praktiker aus Forschung und medizinischer Behandlung, Ethiker und Philosophen, Medizinhistoriker, Rechtswissenschaftler, Pharmakologen, Strahlentherapeuten, Pädiater, Chirurgen und Psychiater mitgearbeitet, die für eine hohe Detailkenntnis und Praxisrelevanz der gesammelten Beiträge bürgen. Das Buch gibt Ethikkommissionsmitgliedern, Forschern und Antragstellern bei Ethikkommissionen einen Einblick in Kriterien und Entscheidungsmechanismen der Forschungsethik und macht Entscheidungen und Beurteilungen von Ethikkommissionen besser verständlich. Darüber hinaus liefert es einen Beitrag zu einer Harmonisierung der bestehenden Praxis.
Convergence and Hybrid Information Technology Yearbook of International Orga
Aus Daten lernen ist das Konzept, das sich in letzter Zeit entwickelt hat. Daten sind ein Konzept, das roher Natur ist und erst nach der Zusammenstellung und derzeit nach der Globalisierung eine Bedeutung erhalten hat. Die Datenmenge in allen Sektoren ist enorm gewachsen. Aus Daten zu lernen ist heutzutage ein sehr beliebtes Konzept, da Unternehmen Daten nur speichern, um daraus zu extrahieren und Analysen durchzuführen, von denen verschiedene andere Faktoren abhängen. Die anderen Faktoren sind hauptsächlich wettbewerbsorientiert und helfen großen Unternehmen, den Markt zu untersuchen und im gegenwärtigen Wettbewerbszeitalter noch stärker zu wachsen. Bei so vielen Daten ist ein weiterer wichtiger Aspekt der Schutz von Daten. Der nächste wichtige Faktor für die Nutzung von Daten ist der Schutz, da der Wettbewerb in allen Bereichen besteht. Das Datenfeld ist keine Ausnahme.
Visualize This! Kluwer Law International B.V.
Interessenkonflikte sind ein schwieriges Thema in der Medizin: Sehr viele Forschungsvorhaben werden vonseiten der Industrie unterstützt, so dass bei Publikationen schnell der Verdacht eines Interessenkonflikts aufkommt. Aber auch niedergelassene Ärzte und ihre Besucher vom pharmazeutischen Außendienst können von solchen Konflikten betroffen sein. In dem Band werden die Hintergründe und Lösungsmöglichkeiten bei Interessenkonflikten aus interdisziplinärer Perspektive beleuchtet.
Law and Economics of Public Procurement Reforms John Wiley & Sons
In the European Union (EU) and its Member States, as elsewhere, the marketing of pharmaceuticals has become subject to an increasingly complex web of legislation and regulation, resulting from the intense scrutiny necessary to ensure such essential products are not only efficacious but 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. A brief overview of how the proposed exit from the EU by the UK will affect the regulatory regime is also included. Following an introductory overview focusing on the regulatory framework for pharmaceuticals in Europe – from its underlying rationales to the relevant committees and agencies – each of fifteen incisive chapters examines a particular process or subject. Among the many topics and issues covered are the following: - obtaining a marketing authorisation; - stages and standards for creating a product dossier; - clinical trials; - how and when an abridged procedure can be used; - criteria for conditional marketing authorisations; - generic products and 'essential similarity'; - paediatric use and the requisite additional trials; - biologicals and 'biosimilars'; - homeopathic and herbal medicines; - reporting procedures; - pharmacovigilance; - parallel trade; - relevant competition law and intellectual property rights; and - advertising. In addition, national variation charts in many of the chapters illustrate eight major jurisdictions (Belgium, France, Germany, Italy, The Netherlands, Spain, Sweden, and the UK). Sample forms and URLs for the most important Directives 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.

Successfully Marketing Clinical Trial Results Routledge
Advocacy is a broad term that covers activities aimed at increasing attention, awareness, information, nursing, treatment, and support to improve the outcome of patients. These actions can be focused directly towards patients or indirectly via third parties. Although advocacy is present in all medical specialties, neurology in particular finds itself in need of strong advocacy tools as the diagnosis, treatment, long-term care and associated resource, and social issues have become increasingly complex. While some physicians implicitly or explicitly act as advocates, there is a lack of holistic research in order to clarify the meaning of advocacy along with concrete methods and strategies. Advocacy in Neurology provides an integrated approach to the concept of advocacy in neurology. Structured in five sections, the book begins by explaining the term "advocacy" in general before elaborating on the areas of interest within neurology. The text goes on to offer concrete strategies and tools for clinicians to deploy advocacy in their daily work, and then discusses specific neurological diseases to point out and explain where advocacy is, or could be, beneficial. The book ends with an outlook, presentation of results, and an ending conclusion. Advocacy in Neurology offers a practical perspective on advocacy activities in neurology, aiming to show when and why they are important for neurology.

House of Commons - Science and Technology Committee: Clinical Trials - HC 104 CRC Press
Contemporary Issues in Marketing brings together theory and practitioners′ perspectives to present a coherent understanding of topical issues in marketing.

Mohr Siebeck
Um Korruptionsrisiken effektiv vorzubeugen und das Vertrauen der Öffentlichkeit zu verbessern, plädieren Pharmaunternehmen für ein aktives Vorgehen gegen kriminelle Handlungsweisen im Gesundheitswesen. Der sog. EFPIA-Kodex des europäischen Dachverbandes der nationalen Verbände forschender Pharmaunternehmen ist eine der untergesetzlichen Normen, die durch Eigeninitiative in der Ärzteschaft und der Pharmabranche vorangetrieben werden, um integres Verhalten in den Mittelpunkt zu stellen. Mit diesem Kodex entschließen sich alle EFPIA-Mitglieder dazu, alle Zahlungen und Zuwendungen aus ihren Geschäftsbeziehungen mit Fachkreisangehörigen und Organisationen des Gesundheitswesens detailliert zu veröffentlichen und der Gesellschaft frei zugänglich zu machen. Die vorliegende Arbeit befasst damit, welche Auswirkungen dieser Kodex auf die betroffenen Pharmaunternehmen hat, welche spezifischen Anforderungen an die Unternehmensführungen gestellt werden und wie den Kodex-Regelungen zur Umsetzung begegnet werden kann, um eine größtmögliche Transparenz zu schaffen.

Health Policy Brief Riva Verlag
Appropriate laws and regulations are essential tools to direct the action of procurers toward the public good and avoid corruption and misallocation of resources. Common laws and regulations across regions, nations and continents potentially allow for the further opening of markets and ventures to newcomers and new ideas to satisfy public demand. Law and Economics of Public Procurement Reforms collects the original contributions related to the new European Union Directives approved in 2014 by the EU Parliament. They are of both economists and lawyers, and have been presented in a manner that allows for exchanges of views and "real time" interaction. This book features, for each section, an introductory exchange between two experts of different disciplines, made up of a series of sequential interactions between an economist and a lawyer, which enriches the liveliness of the debate and improve the mutual understanding between the two professions. Four sections characterize this book: Supporting social considerations via public procurement; Green public procurement; Innovation through innovative partnerships; and Lots - The Economic and Legal Challenges of Centralized Procurement. These themes have current relevance of the new European Public Procurement Directives. Written by an impressive array of experts in their respected fields, this volume is of great importance to practitioners who work in the field of EU public procurement in the Member States of the EU, as well as academics and students who study public finance, public policy and regulation.

Patient Involvement in Health Technology Assessment Edward Elgar Publishing
Der vorliegende Band enthält die auf dem Kolloquium am 25. April 2009 von Klaus Geppert, Ralf Krack und Günter Jakobs gehaltenen Vorträge und wird ergänzt durch Beiträge, die frühere und jetzige Göttinger Kollegen von Fritz Loos zu seinen Ehren verfasst haben. Die einzelnen Aufsätze versuchen mit den Generalthemen Grundfragen des Strafrechts, Rechtsphilosophie und der (unendlichen) Reform der Juristenausbildung einen Teil der Arbeitsschwerpunkte des Jubilars abzudecken. Mit dem Tagungsband verfolgen die Herausgeber das Anliegen, den Lehrer und Wissenschaftler Fritz Loos in möglichst vielen Facetten seiner Person zu würdigen und als seine akademischen Schüler Dank zu sagen für die Förderung, die er uns hat zukommen lassen.

Handbuch Ethik und Recht der Forschung am Menschen Springer
Ein Pharmakonzern wurde durch den Verkauf von Heroin groß. Ein anderer steht im Verdacht, mit falschen Behauptungen über ein Arthritis-Medikament den Tod von Tausenden Patienten verursacht zu haben. Ein weiterer belog die US-amerikanische Food and Drug Administration und wurde zu einer Strafe von 2,3 Milliarden Dollar verurteilt. Dieses Buch handelt von der dunklen Seite der Pharmaindustrie, von der Art und Weise, wie Medikamente entdeckt, produziert, vermarktet und überwacht werden. Es zeigt detailliert auf, wie Wissenschaftler Daten fälschen, um ihre Meinung zu verteidigen. Dabei stehen die Pharmakonzerne der Mafia in nichts nach, sie sind sogar schlimmer und haben mehr Menschenleben auf dem Gewissen. Gøtzsches Buch handelt jedoch nicht nur von Problemen. Der Autor bietet Lösungen, von denen einige größere Erfolgschancen haben als andere, und er zeigt auf eindrückliche Weise die Notwendigkeit für umfassende Reformen.

The Textbook of Pharmaceutical Medicine Springer Nature
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 fourth 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.

Advocacy in Neurology CRC Press
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.

Encyclopedia of Biopharmaceutical Statistics - Four Volume Set Universitätsverlag Göttingen
Mapping Modern Beijing investigates five methods of representing Beijing-a warped hometown, a city of snapshots and manners, an aesthetic city, an imperial capital in comparative and cross-cultural perspective, and a displaced city on the Sinophone and diasporic postmemory-by authors travelling across mainland China, Taiwan, Hong Kong, and overseas Sinophone and non-Chinese communities.

Interessenkonflikte in der Medizin Springer-Verlag
This book provides a scientific and ethical approach to all forms of fraud and misconduct focusing on a scholarly however practice-oriented description of the problems, roots and potential solutions. Organized in dedicated parts, an international team of experts systematically analyzes the most prevalent forms of misconduct, ghost writing, pseudo-science, dubious trials, predatory journals, fake news, mistreatment and harassment, in research, publications, at academic institutions, and in the professional and healthcare environment. A special focus is given to corrective interventions and the role of prevention, education and training. Comprehensive in its scope, the book offers an easy-to-read overview along with a number of real cases for experienced and novice personnel alike. The significance of scientific integrity and research ethics increased during the last couple of years and ethic committees and offices have become an integral part at universities, hospitals, research institutions, government agencies and major private organizations all over the world. Thus, this book provides an indispensable, comprehensive overview across disciplines and for everybody working in research and affiliated institutions. Chapter 37 is available open access under a Creative Commons Attribution 4.0 International License via link.springer.com.

Guide to EU Pharmaceutical Regulatory Law Der EFPIA-Kodex in der pharmazeutischen Industrie: Implementierung eines Controllingsystems zur Sicherstellung seiner Einhaltung
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.

Fraud and Misconduct in Biomedical Research, 4th edition Academic Press
This book draws a unique perspective on the regulation of access to clinical trial data as a case on research and knowledge externalities. Notwithstanding numerous potential benefits for medical research and public health, many jurisdictions have struggled to ensure access to clinical trial data, even at the level of the trial results. Pro-access policy initiatives have been strongly opposed by research-based drug companies arguing that mandatory data disclosure impedes their innovation incentives. Conventionally, access to test data has been approached from the perspective of transparency and research ethics. The book offers a complementary view and considers access to individual patient-level trial data for exploratory analysis as a matter of research and innovation policy. Such approach appears to be especially relevant in the data-driven economy where digital data constitutes a valuable economic resource. The study seeks to define how the rules of access to clinical trial data should be designed to reconcile the policy objectives of leveraging the research potential of data through secondary analysis, on the one hand, and protecting economic incentives of research-based drug companies, on the other hand. Overall, it is argued that the mainstream innovation-based justification for exclusive control over the outcomes of research and development can hardly rationalise trial sponsors’ control over primary data from trials. Instead, access to such data and its robust analysis should be prioritised.

Contemporary Issues in Marketing Oxford University Press
Menschen mit genetischen Behinderungen körperlicher oder seelischer Art gibt es seit Anbeginn der Menschheit. Moderne medizinische Technologien, namentlich die der Präimplantations- und Pränataldiagnostik, eröffnen nicht nur der Medizin, sondern auch der Gesamtgesellschaft die Möglichkeit des präventiven Umgangs mit genetisch bedingten Erkrankungsrisiken. Auf der anderen Seite besteht der gesellschaftliche Anspruch nach einer

Förderung und „Inklusion“ von Menschen mit Behinderung. Diese gegenläufigen Entwicklungen bedürfen der näheren Analyse und kritischen Diskussion. Der vorliegende Band ist aus Vorträgen und Diskussionen eines Expertenworkshops, ausgerichtet vom Institut für Humangenetik am Universitätsklinikum Göttingen in Zusammenarbeit mit dem Göttinger Zentrum für Medizinrecht, hervorgegangen. Ziel dieses Bandes ist es, diese grundlegende Problematik insbesondere aus juristischer wie humangenetischer, aber ebenso aus medizin- wie sozialethischer Sicht vertiefend zu reflektieren.

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