Guide For Investigator Initiated Trials

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The Essential Guide to Pharmacy Residency Research Nursing Knowledge International
Gene transfer research is a rapidly advancing field that involves the introduction of a genetic sequence into a human subject for research or diagnostic purposes. Clinical gene transfer trials are subject to regulation by the U.S. Food and Drug Administration (FDA) at the federal level and to oversight by institutional review boards (IRBs) and institutional biosafety committees (IBCs) at the local level before human subjects can be enrolled. In addition, at present all researchers and institutions funded by the National Institutes of Health (NIH) are required by NIH guidelines to submit human gene transfer protocols for advisory review by the NIH Recombinant DNA Advisory Committee (RAC). Some protocols are then selected for individual review and public discussion. Oversight and Review of Clinical Gene Transfer Protocols provides an assessment of the state of existing gene transfer science and the current regulatory and policy context under which research is investigated. This report assesses whether the current oversight of individual gene transfer protocols by the RAC continues to be necessary and offers recommendations concerning the criteria the NIH should employ to determine whether individual protocols should receive public review. The focus of this report is on the standards the RAC and NIH should use in exercising its oversight function. Oversight and Review of Clinical Gene Transfer Protocols will assist not only the RAC, but also research institutions and the general public with respect to utilizing and improving existing oversight processes.
Defining Drug Courts National Academies Press
The volume and complexity of information about individual patients is greatly increasing with use of electronic records and personal devices. Potential effects on medical product development in the context of this wealth of real-world data could be numerous and varied, ranging from the ability to determine both large-scale and patient-specific effects of treatments to the ability to assess how therapeutics affect patients' lives through measurement of lifestyle changes. In October 2016, the National Academies of Sciences, Engineering, and Medicine held a workshop to facilitate dialogue among stakeholders about the opportunities and challenges for incorporating real-world evidence into all stages in the process for the generation and evaluation of therapeutics. Participants explored unmet stakeholder needs and opportunities to generate new kinds of evidence that meet those needs. This publication summarizes the presentations and discussions from the workshop.
Oncology Clinical Trials ASHP
Clinical Trials, Second Edition, offers those engaged in clinical trial design a valuable and practical guide. This book takes an integrated approach to incorporate biomedical science, laboratory data of human study, endpoint specification, legal and regulatory aspects and much more with the fundamentals of clinical trial design. It provides an overview of the design options along with the specific details of trial design and offers guidance on how to make appropriate choices. Full of numerous examples and now containing actual decisions from FDA reviewers to better inform trial design, the 2nd edition of Clinical Trials is a must-have resource for early and mid-career researchers and clinicians who design and conduct clinical trials. - Contains new and fully revised

material on key topics such as biostatistics, biomarkers, orphan drugs, biosimilars, drug regulations in Europe, drug safety, regulatory approval and more - Extensively covers the "study schema" and related features of study design - Incorporates laboratory data from studies on human patients to provide a concrete tool for understanding the concepts in the design and conduct of clinical trials - Includes decisions made by FDA reviewers when granting approval of a drug as real world learning examples for readers

ClinicalTrials McGraw Hill Professional

The Essential Guide to Pharmacy Residency Research provides pharmacy students, residents, and practitioners with an accessible and practical overview of how to conduct research, empowering them with the self-assurance necessary to initiate and navigate a research project. After reading this book, one will understand that it is entirely possible to complete a high-quality research project within the timeframe allotted during a 1-year residency. Written by Yardlee S. Kauffman, PharmD, MPH, BCACP, CPH and Daniel M. Witt, PharmD, FCCP, BCPS, this book is designed to walk readers through the natural progression of a research project and can be especially helpful for those who don’t know where to begin. Along with expert advice from the authors, former pharmacy residents offer first-hand anecdotes that describe their early research experiences.

Strengthening Forensic Science in the United States National Academies Press

The National Cancer Institute's (NCI) Clinical Trials Cooperative Group Program has played a key role in developing new and improved cancer therapies. However, the program is falling short of its potential, and the IOM recommends changes that aim to transform the Cooperative Group Program into a dynamic system that efficiently responds to emerging scientific knowledge; involves broad cooperation of stakeholders; and leverages evolving technologies to provide high-quality, practice-changing research.

Oversight and Review of Clinical Gene Transfer Protocols Academic Press

In an effort to increase knowledge and understanding of the process of assuring data quality and validity in clinical trials, the IOM hosted a workshop to open a dialogue on the process to identify and discuss issues of mutual concern among industry, regulators, payers, and consumers. The presenters and panelists together developed strategies that could be used to address the issues that were identified. This IOM report of the workshop summarizes the present status and highlights possible strategies for making improvements to the education of interested and affected parties as well as facilitating future planning.

Virtual Clinical Trials Karger Medical and Scientific Publishers

An ideal health care system relies on efficiently generating timely, accurate evidence to deliver on its promise of diminishing the divide between clinical practice and research. There are growing indications, however, that the current health care system and the clinical research that guides medical decisions in the United States falls far short of this vision. The process of generating medical evidence through clinical trials in the United States is expensive and lengthy, includes a number of regulatory hurdles, and is based on a limited infrastructure. The link between clinical research and medical progress is also frequently misunderstood or unsupported by both patients and providers. The focus of clinical research changes as diseases emerge and new treatments create cures for old conditions. As diseases evolve, the ultimate goal remains to speed new and improved medical treatments to patients throughout the world. To keep pace with rapidly changing health care demands, clinical research resources need to be organized and on hand to address the numerous health care questions that continually emerge. Improving the overall capacity of the clinical research enterprise will depend on ensuring that there is an adequate infrastructure in place to support the investigators who conduct research, the patients with real diseases who volunteer to participate in experimental research, and the institutions that organize and carry out the trials. To address these issues and better understand the current state of clinical research in the United States, the Institute of Medicine's (IOM) Forum on Drug Discovery, Development, and Translation held a 2-day workshop entitled Transforming Clinical Research in the United States. The workshop, summarized in this volume, laid the foundation for a broader initiative of the Forum addressing different aspects of clinical research. Future Forum plans include further examining regulatory, administrative, and structural barriers to the effective conduct of clinical research; developing a vision for a stable, continuously funded clinical research infrastructure in the United States; and considering strategies and collaborative activities to facilitate more robust public engagement in the clinical research enterprise.

Envisioning a Transformed Clinical Trials Enterprise in the United States Karger Medical and Scientific Publishers

The “essential” companion to the landmark Users' Guides to the Medical Literature - completely revised and updated! 5 STAR DOODY'S REVIEW! "This second edition is even better than the original. Information is easier to find and the additional resources that will be available at www.JAMAevidence.com will provide readers with a one-stop source for evidence-based medicine."--Doody's Review Service Evidence-based medicine involves the careful interpretation of medical studies and its clinical application. And no resource helps you do it better-and faster-than Users' Guides to the Medical Literature: Essentials of Evidence-Based Clinical Practice. This streamlined reference distills the most clinically-relevant coverage from the parent Users' Guide Manual into one highly-focused, portable resource. Praised for its clear explanations of detailed statistical and mathematical principles, The Essentials concisely covers all the basic concepts of evidence-based medicine--everything you need to deliver optimal patient care. It's a perfect at-a-glance source for busy clinicians and students, helping you distinguish between solid medical evidence and poor medical evidence, tailor evidence-based medicine for each patient, and much more. Now in its second edition, this carry-along quick reference is more clinically relevant--and more essential--than ever! FEATURES Completely revised and updated with all new coverage of the basic issues in evidence-based medicine in patient care Abundant real-world examples drawn from the medical literature are woven throughout, and include important related principles and pitfalls in using clinical research in patient care decisions Edited by over 60 internationally recognized editors and contributors from around the globe Also look for JAMAevidence.com, a new interactive database for the best practice of evidence based medicine.

A Guide to the Scientific Career National Academies Press

Scores of talented and dedicated people serve the forensic science community, performing vitally important work. However, they are often constrained by lack of adequate resources, sound policies, and national support. It is clear that change and advancements, both systematic and scientific, are needed in a number of forensic science disciplines to ensure the reliability of work, establish enforceable standards, and promote best practices with consistent application. Strengthening Forensic Science in the United States: A Path Forward provides a detailed plan for addressing these needs and suggests the creation of a new government entity, the National Institute of Forensic Science, to establish and enforce standards within the forensic science community. The benefits of improving and regulating the forensic science disciplines are clear: assisting law enforcement officials, enhancing homeland security, and reducing the risk of wrongful conviction and exoneration. Strengthening Forensic Science in the United States gives a full account of what is needed to advance the forensic science disciplines, including upgrading of systems and organizational structures, better training, widespread adoption of uniform and enforceable best practices, and mandatory certification and accreditation programs. While this book provides an essential call-to-action for congress and policy makers, it also serves as a vital tool for law enforcement agencies, criminal prosecutors and attorneys, and forensic science educators.

FDA Investigations Operations Manual National Academies Press

Part of "RPS Pharmacy Business Administration Series", this book offers good clinical practice guidelines. It includes standards on how clinical trials should be conducted, provide assurance of safety and efficacy of various drugs and protect human rights.

Institutional Review Board Member Handbook Pharmaceutical Press

An estimated 48 percent of the population takes at least one prescription drug in a given month. Drugs provide great benefits to society by saving or improving lives. Many drugs are also associated with side effects or adverse events, some serious and some discovered only after the drug is on the market. The discovery of new adverse events in the postmarketing setting is part of the normal natural history of approved drugs, and timely identification and warning about drug risks are central to the mission of the Food and Drug Administration (FDA). Not all risks associated with a drug are known at the time of approval, because safety data are collected from studies that involve a relatively small number of human subjects during a relatively short period. Written in response to a request by the FDA, Ethical and Scientific Issues in Studying the Safety of Approved Drugs discusses ethical and informed consent issues in conducting studies in the postmarketing setting. It evaluates the strengths and weaknesses of various approaches to generate evidence about safety questions, and makes recommendations for appropriate followup studies and randomized clinical trials. The book provides guidance to the FDA on how it should factor in different kinds of evidence in its regulatory decisions. Ethical and Scientific Issues in Studying the Safety of Approved Drugs will be of interest to the pharmaceutical industry, patient advocates, researchers, and consumer groups.

Quality of Life Assessment in Clinical Trials CRC Press

When is it appropriate to return individual research results to participants? The immense interest in this question has been fostered by the growing movement toward greater transparency and participant engagement in the research enterprise. Yet, the risks of returning individual research resultsâ€"such as results with unknown validityâ€"and the associated burdens on the research enterprise are competing considerations. Returning Individual Research Results to Participants reviews the current evidence on the benefits, harms, and costs of returning individual research results, while also considering the ethical, social, operational, and regulatory aspects of the practice. This report includes 12 recommendations directed to various stakeholdersâ€"investigators, sponsors, research institutions, institutional review boards (IRBs), regulators, and participantsâ€"and are designed to help (1) support decision making regarding the return of results on a study-by-study basis, (2) promote high-quality individual research results, (3) foster participant understanding of individual research results, and (4) revise and harmonize current regulations.

Registries for Evaluating Patient Outcomes Academic Press

Successful drug development relies on accurate and efficient clinical trials to deliver the best and most effective pharmaceuticals and clinical care to patients. However, the current model for clinical trials is outdated, inefficient and costly. Clinical trials are limited by small sample sizes that do not reflect variations among patients in the real world, financial burdens on participants, and slow processes, and these factors contribute to the disconnect between clinical research and clinical practice. On November 28-29, the National Academies of Sciences, Engineering, and Medicine convened a workshop to investigate the current clinical trials system and explore the potential benefits and challenges of implementing virtual clinical trials as an enhanced alternative for the future. This publication summarizes the presentations and discussions from the workshop.

A National Cancer Clinical Trials System for the 21st Century World Health Organization

"In the new 2016 version of the ethical guidelines, CIOMS provides answers to a number of pressing issues in research ethics. The Council does so by stressing the need for research having scientific and social value, by providing special guidelines for health-related research in low-resource settings, by detailing the provisions for involving vulnerable groups in research and for describing under what conditions biological samples and health-related data can be used for research."--Page 4 de la couverture.

Users' Guides to the Medical Literature National Academies Press

An essential manual for beginners and senior researchers alike For academic medical faculty unfamiliar with national and international regulations, the prospect of initiating and managing a clinical trial can be intimidating. The development of protocols and case report forms, compliance with regulatory requirements, the monitoring of clinical trials as well as the responsibilities of documentation are just some of the tasks the sponsor-investigator is faced with. This book covers the entire spectrum of a clinical trial, reviewing the different stages step by step: financial planning, crucial aspects of trial design, the authorization process and, finally, documentation. Moreover, it contains helpful tips, a practical glossary, instructions and a large number of resources related to the relevant regulations and forms conforming to the International Conference on Harmonization and Good Clinical Practice'. This makes the publication at hand an essential cookbook' for both academic faculty new to clinical trials as well as seasoned sponsors-investigators.

Real-World Evidence Generation and Evaluation of Therapeutics Government Printing Office

Available now to FDA-regulated organizations, this manual allows facility managers to look at their operation's regulatory compliance through the eyes of the government. Because this is the primary reference manual used by FDA personnel to conduct field investigation activities, you can feel confident you are preparing appropriate planning or action. This manual includes revised instructions regarding the release of information and covers FDA's policies and expectations on a comprehensive range of topics: FDA's authority to enter and inspect, inspection notification, detailed inspection procedures, recall monitoring, inspecting import procedures, computerized data requests, federal/state inspection relationships, discussions with management regarding privileged information, seizure and prosecution, HACCP, bioengineered food, dietary supplements, cosmetics, bioterrorism, and product disposition. The manual also includes a directory of Office of Regulatory Affairs offices and divisions.

Developing a Protocol for Observational Comparative Effectiveness Research: A User's

Guide National Academies Press
Clinical trials are the engine of progress in the development of new drugs and devices for the detection, monitoring, prevention and treatment of cancer. A well conceived, carefully designed and efficiently conducted clinical trial can produce results that change clinical practice overnight, deliver new oncology drugs and diagnostics to the marketplace, and expand the horizon of contemporary thinking about cancer biology. A poorly done trial does little to advance the field or guide clinical practice, consumes precious clinical and financial resources and challenges the validity of the ethical contract between investigators and the volunteers who willingly give their time and effort to benefit future patients. With chapters written by oncologists, researchers, biostatisticians, clinical research administrators, and industry and FDA representatives, Oncology Clinical Trials, provides a comprehensive guide for both early-career and senior oncology investigators into the successful design, conduct and analysis of an oncology clinical trial. Oncology Clinical Trials covers how to formulate a study question, selecting a study population, study design of Phase I, II, and III trials, toxicity monitoring, data analysis and reporting, use of genomics, cost-effectiveness analysis, systemic review and meta-analysis, and many other issues. Many examples of real-life flaws in clinical trials that have been reported in the literature are included throughout. The book discusses clinical trials from start to finish focusing on real-life examples in the development, design and analysis of clinical trials. Oncology Clinical Trials features: A systematic guide to all aspects of the design, conduct, analysis, and reporting of clinical trials in oncology Contributions from oncologists, researchers, biostatisticians, clinical research administrators, and industry and FDA representatives Hot topics in oncology trials including multi-arm trials, meta-analysis and adaptive design, use of genomics, and cost-effectiveness analysis Real-life examples from reported clinical trials included throughout
Clinical Trials in Neurology National Academies Press
The Medical Science Liaison (MSL) role was recently reported as one of the best jobs over six figures for healthcare professionals, yet is relatively unknown, even to the medical community. What is a medical science liaison, and what do they do? In this comprehensive must-have guide to the role, the functions of the role of MSL are explored, along with interviews with several MSLs, those that work around them, and most importantly, the customers of the MSL, academic thought leaders. Every healthcare professional, from a pharmacist, to a PhD, to a MD should learn more about one of the greatest jobs that blend business with technical and scientific acumen.
Careers in Clinical Research OUP USA
In spite of recent progress in the harmonization of terminology and processes affecting work on the clinical safety of medicines consensus is needed on standards for many difficult aspects of day-to-day pharmacovigilance that continue to pose problems for both the pharmaceutical industry and drug regulators. The CIOMS V Working Group has generated proposals for pragmatic approaches to dealing with such issues as: classification and handling of individual safety case reports from a variety of sources (spontaneous consumer reports solicited reports literature the Internet observational studies and secondary data bases disease and other registries regulatory ADR databases and licensor-licensee interactions); new approaches to case management and regulatory reporting practices (proper clinical evaluation of cases incidental vs other events patient and reporter identifiability seriousness criteria expectedness criteria case follow-up criteria and the role and structure of case narratives); improvements and efficiencies in the format content and reporting of periodic safety update reports (PSURs) (including results of an industry survey on PSUR workloads and practices; proposals for high case volume and long time-period reports simplification of certain PSURs summary bridging reports addendum reports license renewal reports for EU and Japan dealing with old products and other technical details); determination and use of population exposure (denominator) data (sources of data and a guide to analytical approaches for a variety of circumstances).The Group has also taken stock of the current state of expedited and periodic clinical safety reporting requirements around the world with summary data on regulations from more than 60 countries. Recommendations are made for enhancing the harmonization steps already taken as a result of previous CIOMS publications and the ICH process. In addition to dealing with unfinished and unresolved issues from previous CIOMS initiatives the report covers many emerging topics such as those involving new technologies. Its 20 Appendices provide a wealth of detailed explanations and reference information. It is the most comprehensive and recent treatment of difficult pharmacovigilance issues affecting the working practices and systems of drug safety and other pharmaceutical professionals.
International Ethical Guidelines for Health-Related Research Involving Humans National Academies Press
Cardiac Resynchronization Therapy continues to evolve at a rapidpace. Growing clinical experience and additional clinical trialsare resulting in changes in how patients are selected for CRT. This new edition of the successful Cardiac ResynchronizationTherapy builds on the strengths of the first edition, providingbasic knowledge as well as an up-to-date summary of new advances inCRT for heart failure. Fully updated to include information ontechnological advances, trouble shooting and recent key clinicaltrials, and with nine new chapters, this expanded text provides thelatest information, keeping the reader up-to-date with this rapidlyevolving field. The second edition of Cardiac Resynchronization Therapyis an essential addition to your collection.