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Halcion An Assessment of the CDC Anthrax Vaccine Safety and Efficacy Research Program Safety and efficacy of radiopharmaceuticals 1987 Clinical Safety and Efficacy Testing of Cosmetics Drugs and the FDA Assessing the Efficacy and Safety of Medical Technologies Considerations for Ensuring Safety and Efficacy of Vaccines and Therapeutic Proteins Manufactured by Using Platform Approaches Safe and Effective Medicines for Children Acupuncture: Efficacy, Safety and Practice Clinical Drug Trials Evidence for Safety and Efficacy of Finished Natural Health Products Safety and efficacy of radiopharmaceuticals Acupuncture Mechanism of Action, Safety and Efficacy of Intrauterine Devices Nutraceuticals Natural Medicines Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines Statistical Methods for the Assessment of Safety and Efficacy in HIV Clinical Trials A Randomized Comparative Clinical Trial Evaluating the Safety and Efficacy of Antacids Versus Sucralfate in Preventing Gastrointestinal Bleeding in Critically Ill Pediatric Patiatric Patients The Anthrax Vaccine Advances In Animal Alternatives For Safety And Efficacy Testing The Evidence for the Safety and Efficacy of Metal-On-Metal Hip Prostheses The Prevention and Treatment of Missing Data in Clinical Trials The Safety and Efficacy of Resistance Training for Chronic Heart Failure Patients Drug Efficacy, Safety, and Biologics Discovery Acupuncture Safety and Efficacy of Caffeine Citrate in Premature Infants Decision-making on the Efficacy and Safety of Drugs Clinical Safety and Efficacy of Dhatri Lauha CDC Anthrax Vaccine Safety & Efficacy Research Program Guidance Document Medical readiness : safety & efficacy of the anthrax vaccine The ABACHAI Clinical Trial Protocol: Safety and Efficacy of Abatacept (s.c.) in Patients with CTLA-4 Insufficiency Or LRBA Deficiency: A Non Controlled Phase 2 Clinical Trial Clinical Trials Design Safety and Efficacy of Moringa Oleifera Lamarck (1785) - Therapeutic and Toxicological Properties Safety, Efficacy and Mechanisms of Action of Mesenchymal Stem Cell Therapies International Clinical Trials Technical Working Document for Evaluation of Safety and Efficacy of Teat Dip Formulations Advances in Statistical Methods for the Health Sciences Impact of Safety Monitoring on Efficacy Analyses in Large Confirmatory Group Sequential Trials with Non-trivial Safety Event Rate

Sets out detailed guidelines for conducting scientific research on the safety and efficacy of herbal medicines. The guidelines which reflect the consensus reached by 17 experts in pharmacology biochemistry and traditional medicine respond to the need to assure the safety of widely-used herbal medicines while also facilitating the search for new pharmaceutical products. Specific research criteria are covered together with general principles of investigation including ethical concerns. The book has three parts. The first discusses the special properties of herbal medicines that need to be considered when designing research protocols. The second part provides detailed guidance on the objectives of research the contents of a research protocol and the methods of investigation for non-clinical studies and for Phase I to Phase IV clinical trials. The third part which forms the core of the book presents three sets of research guidelines: for quality specifications of plant materials and preparations for pharmacodynamic and general

pharmacological studies of herbal medicines and for toxicity investigation of herbal medicines. Topics covered range from the information required to establish the identity and quality of plant materials or preparations through the selection of appropriate test systems for pharmacodynamic studies to detailed advice on the many different tests examinations observations and experimental procedures required in experimental animals and controls to establish the safety of herbal medicines. The guidelines are intended to facilitate the work of research scientists and clinicians while also furnishing some reference points for the governmental industrial and non-profit organizations providing financial support. The primary objective of the study is to characterize safety, efficacy and exposure-response relationship of caffeine citrate. The study included the retrospective analysis of clinical data for premature infants who received caffeine citrate per standard of care (SOC), gathered from three sources. Caffeine citrate used at greater doses for longer durations in more immature (e.g., lower Gestational Age) infants than the FDA label appears to be a safe therapy for the treatment of Apnea of Prematurity. Caffeine citrate use is not associated with an increased risk for Necrotizing Enterocolitis." Randomized clinical trials are the primary tool for evaluating new medical interventions. Randomization provides for a fair comparison between treatment and control groups, balancing out, on average, distributions of known and unknown factors among the participants. Unfortunately, these studies often lack a substantial percentage of data. This missing data reduces the benefit provided by the randomization and introduces potential biases in the comparison of the treatment groups. Missing data can arise for a variety of reasons, including the inability or unwillingness of participants to meet appointments for evaluation. And in some studies, some or all of data collection ceases when participants discontinue study treatment. Existing guidelines for the design and conduct of clinical trials, and the analysis of the resulting data, provide only limited advice on how to handle missing data. Thus, approaches to the analysis of data with an appreciable amount of missing values tend to be ad hoc and variable. The Prevention and Treatment of Missing Data in Clinical Trials concludes that a more principled approach to design and analysis in the presence of missing data is both needed and possible. Such an approach needs to focus on two critical elements: (1) careful design and conduct to limit the amount and impact of missing data and (2) analysis that makes full use of information on all randomized participants and is based on careful attention to the assumptions about the nature of the missing data underlying estimates of treatment effects. In addition to the highest priority recommendations, the book offers more detailed recommendations on the conduct of clinical trials and techniques for analysis of trial data. Globally, natural medicine has been considered as an important alternative to modern allopathic medicine. Although natural medicines are popular in society, only limited medicinal herbs have been scientifically evaluated for their potential in medical treatment. This book connects various aspects of the complex journey from traditional medicine to modern medicine. It provides information on topics including global regulations and regulatory hurdles, diverse nutritional challenges and potential health benefits, novel food innovations especially seed-to-clinic approaches, and future trends. FEATURES • Provides information on sustainable use of natural products in the development of new drugs and clinically validated herbal remedies • Discusses issues on evaluation and clinical aspects of herbal medicine, promotion and development, safety evaluation, metabolite profiling, biomarker analysis, formulation, and stability testing • Describes traditional uses of natural medicine through identification, isolation and structural characterization of their active components • Elucidates mechanisms of biological action, adverse effects and identification of their molecular targets of natural medicine • Multidisciplinary appeal including chemistry, pharmacology, pharmacognosy and cell and molecular biology, as well as integration with clinical medicine This book serves as an essential

guide for individuals researching natural medicines, and industry employees in areas including drug development, pharmacology, natural products chemistry, clinical efficacy, ethnopharmacology, pharmacognosy, phytotherapy, phyto-technology and herbal science. Presents up-to-date concepts and approaches to the theory and practice of alternatives to animal testing and promotes technology transfer. The text addresses some of the ramifications of the National Institutes of Health Revitalization Act of 1993 which instructs the NIH to fund replacement, reduction and refinement alternatives. It also describes Drug Efficacy, Safety, and Biologics Discovery: Emerging Technologies and Tools covers key emerging technologies in pharmaceutical R & D and how they have substantially impacted (or are currently impacting) drug discovery. The cross-disciplinary collaborations implicit in integrating these technologies with drug discovery operations will fuel the engine for future innovations. This book cuts across the multiple areas of drug discovery, each chapter authored by pioneers in that field, making for a broad appeal to the chemical and biological scientists and technologists involved in drug discovery and development. This book investigates the scientific basis and efficacy of acupuncture and the quality of training and standards of competence in its practitioners. Patients are increasingly asking about CAM alternatives to orthodox medical practices as they fear the side-effects of ever more potent traditional drug therapy. The book discusses the important issues of safety and the education and training of acupuncture specialists. In addition the book investigates GP's attitudes to acupunture and the extent to which they offer the treatment to their patients. At the 1998 Annual Representative Meeting of the BMA a resolution was passed that the Board of Science and Education should "investigate the scientific basis and efficacy of acupuncture and the quality of training and standards of competence in its practitioners". This report summarizes literature sources and research on acupuncture, looks at safety aspects including the treatment's adverse effects, discusses education and training guidelines, presents results from a survey of UK GPs and suggests future developments for acupuncture, particularly its increased incorporation into the NHS. It will provide doctors, patients, researchers and purchasers of healthcare with information on this most widely used therapy of complementary and alternative medicine, enabling them to become more informed on the value of acupuncture and its likely place within the NHS. Evaluation of different treatments for HIV should take into account the relative balance of safety and efficacy for each treatment. Often time in HIV clinical trials the primary efficacy outcome measure is time to virologic failure, analyzed in an intention-to-treat manner ignoring the changes from the randomized regimens which occur in a reasonable proportion of study participants, often due to treatment limiting adverse events. Clinically, there is therefore considerable interest in also comparing regimens with respect to the competing outcomes of virologic failure and treatment-limiting adverse events leading to discontinuation of the initial randomized regimen. Nutraceuticals: Efficacy, Safety and Toxicity, Second Edition, brings together everything that is currently known about nutraceuticals and their potential toxic effects. The book introduces readers to nutraceuticals, herbal medicines, Ayurvedic medicines, prebiotics, probiotics, adaptogens, and their uses and specific applications. This essential reference discusses the mechanism of action for the judicious use of these nutraceuticals and the best tools for their evaluation before detailing the safety and toxicity of nutraceuticals and interactions with other therapeutic drugs. Finally, and crucially, regulatory aspects from around the world are covered. Completely revised and updated, this updated edition provides toxicologists, pharmacologists, pharmaceutical scientists, and those interested in medicinal plants and natural products with a comprehensive overview of the most effective tools upon which to evaluate the safety and toxicity of nutraceuticals, prebiotics, probiotics and alternative medicines. Presents a completely revised and updated resource on the impact of nutraceuticals and various

disease states such as diabetes and ophthalmic and dermal diseases Grants an overview of the current state-of-the-science of nutraceuticals, their use and applications, and known adverse effects Provides effective tools to evaluate the potential toxicity of any nutraceutical Includes details of regulatory issues as written by international experts The vaccine used to protect humans against the anthrax disease, called Anthrax Vaccine Adsorbed (AVA), was licensed in 1970. It was initially used to protect people who might be exposed to anthrax where they worked, such as veterinarians and textile plant workers who process animal hair. When the U. S. military began to administer the vaccine, then extended a plan for the mandatory vaccination of all U. S. service members, some raised concerns about the safety and efficacy of AVA and the manufacture of the vaccine. In response to these and other concerns, Congress directed the Department of Defense to support an independent examination of AVA. The Anthrax Vaccine: Is It Safe? Does It Work? reports the studyâ€™s conclusion that the vaccine is acceptably safe and effective in protecting humans against anthrax. The book also includes a description of advances needed in main areas: improving the way the vaccine is now used, expanding surveillance efforts to detect side effects from its use, and developing a better vaccine. Safety and Efficacy of Radiopharmaceuticals was established as a very important and comprehensive subject at the First Europe an Symposium on Radiopharmacy and Radiopharmaceuticals in Denmark in 1983. The interest in this subject has grown considerably since then due to the growing interest among national authorities to deal with radiopharmaceuticals. The introduction in recent years of nuclear medicine techniques based on radioactive labelled cells and on monoclonal antibodies has stressed the importance of a well functioning approval system for the clinical trial and use of new radiopharmaceuticals. The process of transferring the experience from the non radioactive drug field into the area of radiopharmaceuticals is still ongoing. International organisations such as the World Health Organisa tion is also including this into their quality assurance programme from both the radiopharmaceutical and the radiation hygiene point of view. In order to give an up-to date survey of these areas, experts were invited to prepare review papers under the following headings: Safety and Efficacy of Radiophar maceuticals with Emphasis on Biological Products, Radiophar macy/Radiation Hygiene, Legal Aspects of the Introduction of New Radiopharmaceuticals and some selected aspects of Good Radiopharmacy Practice. Regulatory agencies within the United States and the United Kingdom, among several other countries, have reviewed extensively the safety and efficacy of Halcion (triazolam)â€"a once commonly used hypnotic drug. Concerns began to emerge about the safety of Halcion when a Dutch physician reported a possible link between it and a syndrome that included such effects as depression, amnesia, hallucinations, and increased anxiety. In addition, in 1991 its manufacturer, Upjohn, noted that "errors had been identified in a report of one of the clinical studies included in the original" application for approval. Since then, the drug has been removed from the market in several countries, whereas in the United States and Canada, the drug's labeling has been modified to reduce the recommended dose and duration of treatment and to heighten awareness of possible side effects. Yet different data and analyses have resulted in conflicting messages that are difficult to reconcile and interpret. In response to a request from the Food and Drug Administration to resolve these controversial issues related to the safety and efficacy of Halcion, this IOM book assesses the adequacy of the drug's clinical trials; the quality and quantity of data on adverse reactions; overall confidence in the data on effectiveness, adverse events, and side effects at different doses; and whether additional studies are needed. A major goal of the US Department of Defense (DOD) Transformational Medical Technologies Initiative (TMTI) is to develop countermeasures that will protect military personnel against bioweapons, including specific infectious-disease agents and toxins. An explicit TMTI objective is to respond quickly to

such threats by producing an appropriate amount of an effective countermeasure-currently defined as enough material to treat or vaccinate 3 million personnel-within 12 months of identification of a specific threat. DOD officials call for TMTI programs to be up and running by 2014. The National Academies hosted a workshop which brought together scientists from academe, government, and the biotechnology industry to identify and discuss challenges and ideas related to the TMTI's vision of developing countermeasures within a few months after an agent is identified. The workshop focused on manufacturing processes and specifically on the development of "manufacturing platforms"-repeatable components of manufacturing that reduce both development time and risk. An underlying assumption was that demonstrating that integrated platforms can reliably produce safe and efficacious countermeasures might shorten the regulatory approval process. The workshop is summarized in this book. In 1998, the Department of Defense (DoD) began a program of mandatory immunization against anthrax for all military personnel. As the program proceeded, however, some military personnel and their families raised concerns about the safety and efficacy of the anthrax vaccine. Acknowledging both the need to protect military personnel and the concerns about the anthrax vaccine, congress directed the Centers for Disease Control and Prevention (CDC) to carry out a research program on its safety and efficacy. To assist in the development of this program, CDC requested the Institute of Medicine (IOM) to convene a committee to review the completeness and appropriateness of the research program. In An Assessment of the CDC Anthrax Vaccine Safety and Efficacy Research Program, the committee makes an overall assessment of the CDD research plan and reviews the specific studies proposed by CDC in the three areas of efficacy, safety and acceptability. The committee also notes additional research needs that became evident following the bioterrorist events of 2001 and makes recommendations about the leadership of the research program. Essay from the year 2017 in the subject Medicine - Orthopedy, grade: 1, Egerton University, language: English, abstract: Metal-on-metal hip prostheses have been in use clinical since 1960s, and their safety and efficacy has never been reviewed adequately. The current reports of metal-on-metal hip implants' failure have led to health concernsits. Literature review has been showing diverse changes. Clinical studies have been conducted to ascertain the usefulness of the technology in regard to its safety and efficacy. Ordinarily, metal-on-metal total hip implants are believed to release toxic substances in the patient's body, causing significant health concerns of the technology. Therefore, this paper will provide a critical review on the evidence for the safety and efficacy of metal-on-metal hip prostheses, primarily with regard to its insufficiency. This document assists with the classification of safety and efficacy changes made to a new drug that has received a Notice of Compliance (NOC) pursuant to paragraph C.08.004 (1) (a) of the Food and Drug Regulations, and to provide sponsors with recommendations on what would be considered sufficient data to support a proposed label change and to allow a determination of the impact of the change on the safety, efficacy or effective use of a new drug.--Includes text from document. Abstract: Background Cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) insufficiency and lipopolysaccharide-responsive and beige-like anchor protein (LRBA) deficiency are both complex immune dysregulation syndromes with an underlying regulatory T cell dysfunction due to the lack of CTLA-4 protein. As anticipated, the clinical phenotypes of CTLA-4 insufficiency and LRBA deficiency are similar. Main manifestations include hypogammaglobulinemia, lymphoproliferation, autoimmune cytopenia, immune-mediated respiratory, gastrointestinal, neurological, and skin involvement, which can be severe and disabling. The rationale of this clinical trial is to improve clinical outcomes of affected patients by substituting the deficient CTLA-4 by administration of CTLA4-Ig (abatacept) as a causative personalized treatment. Objectives Our objective is to assess the safety and efficacy of abatacept

for patients with CTLA-4 insufficiency or LRBA deficiency. The study will also investigate how treatment with abatacept affects the patients' quality of life. Methods /Design: ABACHAI is a phase IIa prospective, non-randomized, open-label, single arm multi-center trial. Altogether 20 adult patients will be treated with abatacept 125 mg s.c. on a weekly basis for 12 months, including (1) patients already pretreated with abatacept, and (2) patients not pretreated, starting with abatacept therapy at the baseline study visit. For the evaluation of drug safety infection control during the trial, for efficacy, the CHAI-Morbidity Score will be used. Trial registration The trial is registered in the German Clinical Trials Register (Deutsches Register Klinischer Studien, DRKS) with the identity number DRKS00017736, registered: 6 July 2020, https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00017736 The Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) were designed to encourage more pediatric studies of drugs used for children. The FDA asked the IOM to review aspects of pediatric studies and changes in product labeling that resulted from BPCA and PREA and their predecessor policies, as well as assess the incentives for pediatric studies of biologics and the extent to which biologics have been studied in children. The IOM committee concludes that these policies have helped provide clinicians who care for children with better information about the efficacy, safety, and appropriate prescribing of drugs. The IOM suggests that more can be done to increase knowledge about drugs used by children and thereby improve the clinical care, health, and well-being of the nation's children. Safety and Efficacy of Moringa oleifera Lamarck (1785) - Therapeutic and Toxicological Properties. Statistical methods have become an increasingly important and integral part of research in the health sciences. Many sophisticated methodologies have been developed for specific applications and problems. This self-contained comprehensive volume covers a wide range of topics pertaining to new statistical methods in the health sciences, including epidemiology, pharmacovigilance, quality of life, survival analysis, and genomics. The book will serve the health science community as well as practitioners, researchers, and graduate students in applied probability, statistics, and biostatistics. How the FDA was shaped by public health crises and patient advocacy, told against a background of the contentious hearings on the breast cancer drug Avastin. Food and Drug Administration approval for COVID-19 vaccines and the controversial Alzheimer’s drug Aduhelm made headlines, but few of us know much about how the agency does its work. Why is the FDA the ultimate US authority on a drug’s safety and efficacy? In Drugs and the FDA, Mikkael Sekeres—a leading oncologist and former chair of the FDA’s cancer drug advisory committee—tells the story of how the FDA became the most trusted regulatory agency in the world. It took a series of tragedies and health crises, as well as patient advocacy, for the government to take responsibility for ensuring the efficacy and safety of drugs and medical devices. Before the FDA existed, drug makers could hawk any potion, claim treatment of any ailment, and make any promise on a label. But then, throughout the twentieth century, the government was forced to take action when children were poisoned by contaminated diphtheria and smallpox vaccines, an early antibiotic contained antifreeze, a drug prescribed for morning sickness in pregnancy caused babies to be born disfigured, and access to AIDS drugs was limited to a few clinical trials while thousands died. Sekeres describes all these events against the backdrop of the contentious 2011 hearings on the breast cancer drug Avastin, in which he participated as a panel member. The Avastin hearings, he says, put to the test a century of the FDA’s evolution, demonstrating how its system of checks and balances works—or doesn’t work. Safety and efficacy of radiopharmaceuticals are elements of great importance in nuclear medicine. Since the first meeting in 1965 in Oak Ridge with the title Radiopharmaceuticals tremendous developments have taken place. In 1965 the whole technetium-99m area was just in

its very beginning. Safety and efficacy of the non-radioactive pharmaceuticals have attracted great attention during the last 10 years and so have similar aspects of radiopharmaceuticals during the later years. Regulatory agencies are extending their work also to the preparation of radiopharmaceuticals at hospitals and to requirements for registration of radiopharmaceuticals. In a fast developing field there might be tendencies to confrontation between interests and there have certainly been some tendencies to put undue restrictions on the use of radio pharmaceuticals due to the lack of understanding between the industry and the regulatory authorities and between regulatory authorities and hospitals. Much of this may have been due to lack of information and certainly is due to the lack of fundamental scientific knowledge in many radiopharmaceutical aspects. A fast and safe introduction of new radio pharmaceuticals and the proper handling of these requires a lot of development work, but also an understanding of how general principles from the non-radioactive drug field may be sensibly transformed into the radiopharmaceutical area. It may even require compromises between requirements for safety in different areas such as radiation protection and pharmaceutical aspects. This book investigates the scientific basis and efficacy of acupuncture and the quality of training and standards of competence in its practitioners. Patients are increasingly asking about CAM alternatives to orthodox medical practices as they fear the side-effects of ever more potent traditional drug therapy. The book discusses the important issues of safety and the education and training of acupuncture specialists. In addition the book investigates GP's attitudes to acupunture and the extent to which they offer the treatment to their patients.

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