

Review of the Fialuridine (FIAU) Clinical Trials

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Curtis L. Meinert PhD



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Review of the Fialuridine (FIAU) Clinical Trials Institute of Medicine, Committee to Review the Fialuridine (FIAU/FIAC) Clinical Trials, 1995-03-14 In June 1993 a clinical trial of fialuridine FIAU a promising new medication for hepatitis B was abruptly terminated when one of the 15 out patients participating in the National Institutes of Health NIH study was suddenly hospitalized with liver failure Although all the remaining patients were contacted and told to stop taking their medication six more subsequently developed severe toxicity Five patients died and two others were probably saved from death only by having liver transplants In response to a request from the Secretary of the Department of Health and Human Services the IOM committee has analyzed the FIAU clinical trials making recommendations for additional safeguards for the conduct of future clinical trials This evaluation included the review of documents pertaining to investigational new drug submissions protocols and consent forms from other clinical trials as well as information available from other clinical and preclinical experience with compounds related to FIAU and its parent drug fiacitibine FIAC which is metabolized to FIAU The committee does not seek to affix responsibility for the adverse outcome of this NIH trial but instead focuses on whether any rules or procedures governing the clinical trials process itself need to be changed and if so what burdens or costs such changes might place on future clinical trials

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Principles and Practice of Clinical Research John I. Gallin, Frederick P Ognibene, 2011-04-28 The second edition of this innovative work again provides a unique perspective on the clinical discovery process by providing input from experts within the NIH on the principles and practice of clinical research Molecular medicine genomics and proteomics have opened vast opportunities for translation of basic science observations to the bedside through clinical research As an introductory reference it gives clinical investigators in all fields an awareness of the tools required to ensure research protocols are well designed and comply with the rigorous regulatory requirements necessary to maximize the safety of research subjects Complete with sections on the history of clinical research and ethics copious figures and charts and sample documents it serves as an excellent companion text for any course on clinical research and as a must have reference for seasoned researchers Incorporates new chapters on Managing Conflicts of Interest in Human Subjects Research Clinical Research from the Patient's Perspective The Clinical Researcher and the Media Data Management in Clinical Research Evaluation of a Protocol Budget Clinical Research from the Industry Perspective and Genetics in Clinical Research Addresses the vast opportunities for translation of basic science observations to the bedside through clinical research Delves into data management and addresses how to collect data and use it for discovery Contains valuable up to date information on how to obtain funding from the federal government

An Insider's Guide to Clinical Trials Curtis L Meinert, 2011-05-18 This book serves as an invaluable guide on how clinical trials are designed and run how to interpret the results and what to make of them in general The book includes shopping guides for trials a list of common abbreviations used by trialists and tools for patients for deciding if or when to enroll in a clinical trial

Clinical Trials Handbook Curtis L. Meinert, 2012-10-10 A systematic approach to all aspects of designing and conducting clinical trials The success or failure of clinical trials hinges on hundreds of details that need to be developed often under less than ideal conditions Written by one of the world's leading trialists Clinical Trials Handbook Design and Conduct provides clinicians with a complete guide to designing conducting and evaluating clinical trials teaching them how to simplify the process and avoid costly mistakes The author draws on his extensive clinical trials experience to outline all steps employed in setting up and running clinical trials from budgeting and

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Cobert's Manual of Drug Safety and Pharmacovigilance Barton Cobert,2011-03-30 Completely revised and updated the Manual of Drug Safety and Pharmacovigilance Second Edition is a how to manual for those working in the fields of drug safety clinical research pharmacuetucal regulatory affairs government and legal professions This comprehensive and practical guide discusses the theory and the practicalities of drug safety also known as pharmacovigilance and side effects as well as providing essential information on drug safety and regulations including recognizing monitoring reporting and cataloging serious adverse drug reactions The Manual of Drug Safety and Pharmacovigilance Second Edition teaches the ins and outs of drug safety in the industry hospitals FDA and other health agencies both in the US and around the world and presents critical information about what is done when confronted with a drug safety problem

ClinicalTrials Curtis L. Meinert PhD,2012-02-17 First published in 1986 this landmark text is the definitive guide to clinical trials written by one of the leading experts in the field This fully updated second edition continues to be the most authoritative reference text on randomized clinical trials It contains a wealth of practical information on the design conduct and analysis of both single center and multicenter trials No other book on clinical trials offers as much detail on such issues as sample size calculation stratification and randomization data systems design development of consent forms publication policies preparation of funding requests and reporting procedures While the basics of design conduct and analysis of clinical trials remain the same there have been significant changes since the first edition of Clinical Trials was published two decades ago In this new edition the author discusses the refinements and improvements made to methods and procedures changes in the policies and guidelines underlying trials as well as requirements for registration of trials He also discusses current practices for data sharing for gender representation for treatment effects monitoring and for ethical standards of clinical trials The importance of the randomized controlled trial has grown significantly over time and they are now the cornerstone of all evidence based medicine Still rich in tables checklists charts and other resources for the trialist the second edition of Clinical Trials is an indispensable reference for clinicians biostatisticians epidemiologists and anyone involved in the design and implementation of a clinical trial

Clinical Trials Dictionary Curtis L. Meinert,2012-08-28 A thoroughly updated new edition of the essential reference on the design practice and analysis of clinical trials Clinical Trials

Dictionary Terminology and Usage Recommendations Second Edition presents clear precise meticulously detailed entries on all aspects of modern day clinical trials Written and compiled by one of the world s leading clinical trialists this comprehensive volume incorporates areas of medicine statistics epidemiology computer science and bioethics providing a treasure trove of key terms and ideas This new edition continues to supply readers with the A Z terminology needed to design conduct and analyze trials introducing a vocabulary for the characterization and description of related features and activities More than 300 new entries are now included reflecting the current usage practices and conventions in the field along with usage notes with recommendations on when to use the term in question Detailed biographical notes highlight prominent historical figures and institutions in the field and an extensive bibliography has been updated to provide readers with additional resources for further study The most up to date work of its kind Clinical Trials Dictionary Second Edition is an essential reference for anyone who needs to report on index analyze or assess the scientific strength and validity of clinical trials

Clinical Research Informatics Rachel L. Richesson, James E. Andrews, Kate Fultz Hollis, 2023-06-14 This extensively revised new edition comprehensively reviews the rise of clinical research informatics CRI It enables the reader to develop a thorough understanding of how CRI has developed and the evolving challenges facing the biomedical informatics professional in the modern clinical research environment Emphasis is placed on the changing role of the consumer and the need to merge clinical care delivery and research as part of a changing paradigm in global healthcare delivery Clinical Research Informatics presents a detailed review of using informatics in the continually evolving clinical research environment It represents a valuable textbook reference for all students and practising healthcare informatics professional looking to learn and expand their understanding of this fast moving and increasingly important discipline

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