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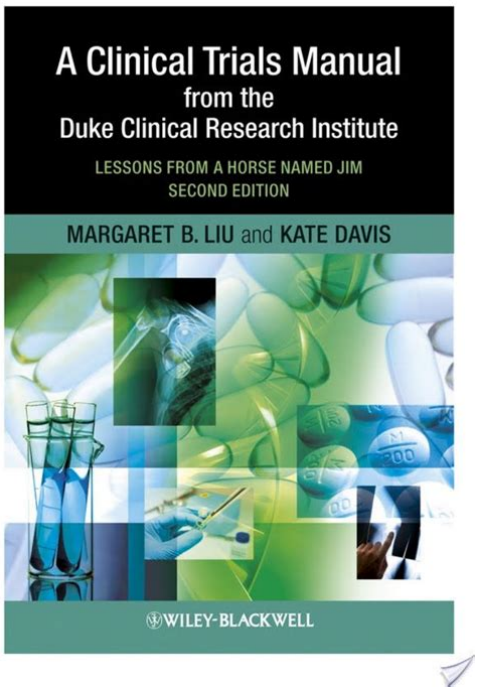

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This graphically appealing and eminently readable manual also provides sample forms and worksheets to facilitate data management and regulatory record retention; these can be modified and adapted for use at investigative sites. Kate Davis is Business Development Specialist for DCRI Communications Group, Durham, NC, US. Lessons from a horse named Jim. Published by WileyBlackwell Chichester, UK. 2010. 406 pp, ISBN 9781405195157. Author information Article notes Copyright and License information Disclaimer Quintiles, Bracknell, Berkshire, UK Dipti Amin, Station House, Market Street, Bracknell, Berkshire, RG12 1HX, UK. Lessons from a horse named Jim' is the second edition of this practical guide to conducting clinical trials written from the investigator perspective and authored by Margaret Liu and Kate Davis, both with personal experience of conducting trials. It sets out with the intent to provide novice clinical researchers with a manual on how to conduct clinical trials of medicines and devices and the particular points of importance for an investigator. There is much practical advice on how to achieve trial success while ensuring the vital tenets of patient safety and data integrity. Chapters 8 through to 14 are full of practical steps, tips and factors to consider when carrying out an investigational medicinal product or device trial in patients. The last chapter brings in the international perspective on clinical trials with its focus on crosscultural sensitivities, the impact and importance of genetic variations, ongoing initiatives and the advances made in the big infectious diseases that still kill millions worldwide such as malaria, TB, HIV, and where the authors believe future efforts should be directed. My particular favourite was the first chapter with the historical background which was enjoyable reading in itself, whilst for those new to clinical trials it helps put a perspective on the necessity for heavy regulation and governance in this domain.

The extensive appendices provide a valuable resource for key reference documents and templates for use in clinical trials. The authors do make it clear that this is a book primarily about interventional clinical trials of drugs and devices with a brief reference to noninterventional trials. There is excellent use of boxed information providing summaries of topics discussed, anecdotes and examples to illustrate points made in the text, historical snippets such as the origin of randomization, examples of trials demonstrating a particular design or endpoint, to emphasize key points, as well as content summary boxes at the start of chapters. One that particularly appealed to me is the use of quotes at the beginning of chapters. All these different additions help to animate what could otherwise make for rather dry reading. It is clear from the examples provided, such as the optimum way to ask subjects about adverse events without biasing the response and other references to the practicalities of study conduct, that the authors have been involved in conducting trials handson and have a clear understanding of the responsibilities of investigators although neither is a clinician. It was pleasing to see that safety reporting is given appropriate importance with a chapter dedicated to describing what needs to be reported to whom, when and why. Chapter 11 provides good practical tips on keeping patients motivated and maximizing retention on studies although I cant help wondering how many investigators have the time and resources to do all this

realistically, especially without a Clinical Research Coordinator. This book is written in easy to read, simple language that eases assimilation of the information. The layout is friendly to the eye and enhances information absorption. It is however, UScentric in its description of processes, procedures and requirements from a regulatory and ethics perspective.

There are extensive references to the US Code of Federal Regulations throughout with some general references to global standards such as ICH GCP. Whilst this is understandable given that the USA is a major research arena and the single biggest market for medicines, more references to regulations and ethical requirements in Europe would have enhanced the utility of this book outside the USA. Nonetheless, although this book may have been written for primarily a US readership, it is a useful text for understanding the principles and the practical elements of clinical trial conduct, and a useful manual for anyone wishing to conduct clinical trials anywhere in the world. Competing Interests DA is the Senior Vice President and Chief Compliance Officer at Quintiles Transnational and declares this in the interest of transparency. Articles from British Journal of Clinical Pharmacology are provided here courtesy of British Pharmacological Society. Some features of WorldCat will not be available.By continuing to use the site, you are agreeing to OCLC's placement of cookies on your device. Find out more here. Numerous and frequentlyupdated resource results are available from this WorldCat.org search. OCLC's WebJunction has pulled together information and resources to assist library staff as they consider how to handle coronavirus issues in their communities.However, formatting rules can vary widely between applications and fields of interest or study. The specific requirements or preferences of your reviewing publisher, classroom teacher, institution or organization should be applied. Please enter recipient email addresses. Please reenter recipient email addresses. Please enter your name. Please enter the subject. Please enter the message. Author Margaret B Liu; Kate Davis; Duke Clinical Research Institute. Publisher Chichester, West Sussex, UK; Hoboken, NJ WileyBlackwell, 2010.Please select Ok if you would like to proceed with this request anyway. All rights reserved.

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