Book review

A Clinical Trials Manual from the Duke Clinical Research Institute. Lessons from a horse named Jim

Margaret B Liu & Kate Davis. Published by Wiley-Blackwell, Chichester, UK, 2010. 406 pp, ISBN: 978-1-4051-9515-7

'A Clinical Trials Manual from the Duke Clinical Research Institute. 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 1–7 provide the background to clinical trials, the historical evolution, overview of the relevant regulations and key activities such as monitoring and audits. 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 cross-cultural sensitivities, the impact and importance of genetic variations, on-going 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 non-interventional trials. However, there is a worrying use of phraseology on page 40 which suggests that it is acceptable to carry out studies for the purpose of familiarizing physicians with a new drug and increasing its usage; this may not have been the meaning intended but it reads as if 'seeding' studies are being endorsed.

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 hands-on and have a clear understanding of the responsibilities of investigators although neither is a clinician. More emphasis could have been given to the importance of robust inclusion and exclusion criteria for the successful implementation of a protocol which I felt was not strong despite there being a whole chapter devoted to 'Study Feasibility: Protocol Review'. 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 can't help wondering how many investigators have the time and resources to do all this realistically, especially without a Clinical Research Co-ordinator. There are some amusing gems such as in Chapter 5 where it states 'IRB members must be individuals of both sexes' – (only hermaphrodites eligible then?!) and in Chapter 12 where it advises retaining a blank copy of the revised consent form whereas the intent was probably to suggest keeping one that was unsigned!

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, US-centric 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.

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