

A Quick Guide to Clinical Trials (Paperback)



Clinical trials are at the heart of the successful development of new medicines for patients. Like any other specialized area, clinical trials has a vocabulary and jargon all its own and the processes involved are highly standardized for ethical, practical and regulatory reasons. No matter. Most people can get a grip on the topic in sufficient detail to understand in general terms what people are talking about. The first part of this book provides a helicopter view of the clinical trials process with Chapter 1 explaining why we do what we do as a broad structure into which the later process chapters will fit. The second chapter reviews the history of clinical trials per se and the evolving ethical and regulatory considerations (i.e., how we got to where we are). Complementing these two chapters is the commercial perspective: the imperative for moving forward. Armed with these three chapters as background, the succeeding nuts and bolts process chapters will fall into place. You will be able to see exactly how any given discipline fits in and plays its part in delivering the overall clinical trial program. For make no mistake, the successful design, execution and delivery of an effective clinical trial program relies on excellent cooperation, understanding and respect within an often widely dispersed multi-disciplinary team. We specifically set out to ask experienced clinical researchers from all the relevant disciplines to write succinct and straightforward chapters which would explain what their role is and how this fits into a very exciting big picture, overall. In addition, we felt it was very important to acknowledge the role of the patient because without their participation no clinical trial would proceed. Frequently, it is the enthusiasm and dedication of patients that keep clinical trials on track. There is currently a great need for a better public support of clinical trials, but this can only

happen if both patients and clinical trial researchers fully engage with each other. Many clinical researchers are highly experienced in the operational and regulatory aspects of trials, but how many of them have actually become involved as a patient? The answer is probably very few! In combination with the other contributions, Chapter 13 helps fill this gap as it is written by someone who has both worked on clinical trials and yet also participated as a patient. We have tried to present these chapters in a logical way so that the flow of the clinical trials process is also apparent. This is rather artificial, as it will be clear to those who read the book straight through, that many activities happen in parallel and that while there is relatively little down time for any specific group, there are often times of frenzied activity! Each chapter also stands alone as a quick dip foundation or refresher. Everyone involved in clinical trials finds it demanding to keep up-to-date with current developments in the field. Therefore, as a final aspect to the book we have tried to explore what the future of clinical trials might be. There are numerous factors that have shaped clinical trials until now and far more that will influence their development in the future. We can only guess at what the future of clinical trials might be, but one certainty is that we will continue to rely on them for the development of new medicines. We believe you will come away with a really good basic grasp of the excitement of the clinical trials process, its drivers, checks and balances, and how you may even be able to contribute in a wide variety of ways.

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