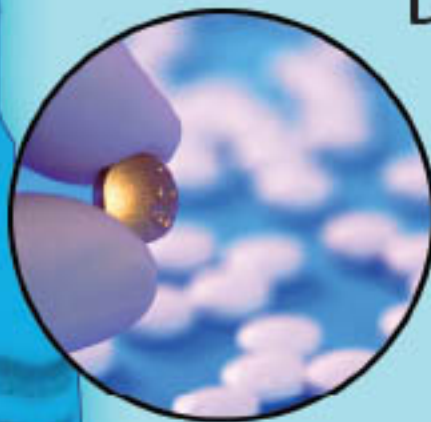
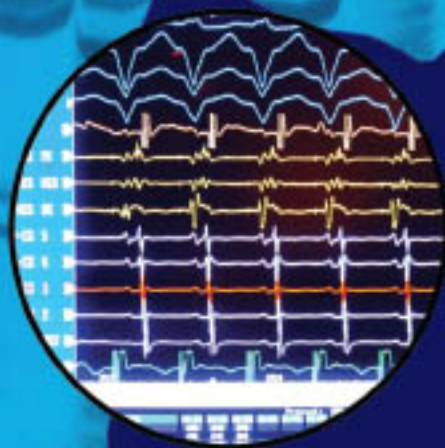




# *A quick guide<sup>TM</sup> to clinical trials*

*"for people  
who may not  
know it all"*



EDITED BY:

**Drs. Madhu Davies and  
Faiz Kermani**

*A quick guide™ to  
clinical trials*

*“for people who may not  
know it all”*

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# *Acknowledgment*

This book was inspired by the enthusiasm about clinical trials shown by the many new recruits to the pharmaceutical industry we have met at scientific meetings we have attended over the years. It is also the book Madhu would have liked to have read when she joined the industry in 1993.

The book would not have been possible without the corresponding commitment shown by the authors, all of whom are well established experts in their fields and yet retain the ability to communicate on a level accessible to non-expert readers. And the imagination of the publisher, Eric Langer. We thank you all.

Both of us are particularly grateful to our own long suffering families who have provided cheerful support (and many cups of tea) during the gestation of this book.

For Miranda, Julia and Isis: keep asking those tricky questions; retain that curiosity!

Madhu Davies and Faiz Kermani



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\* **Dr. Graham Wylie** is Chief Executive Officer of the Medical Research Network Ltd, an affiliate company of Healthcare at Home. Graham has 17 years experience in clinical trials, starting with 10 years at Pfizer in Clinical Development and Corporate HQ, with roles ranging from project management of trials to global implementation of standard trial processes and IT tools. He then joined Parexel International in 1999 as Medical Director for Northern Europe, progressing to Vice President of Account Management for Europe by 2003. In 2005 he joined Healthcare at Home to develop their clinical trials activities into a full business unit, known as 'The Medical Research Network', spinning the division off as a separate company in 2006. The MRN provides Site Support, placing nurses in research sites; Home Trial Support, with nurses visiting patients in their own home for some trial visits and other services designed to directly address the needs of the UK research academic and pharmaceutical community.

# ***Introduction***

## ***A quick guide to clinical trials: “a book for people who may not know it all”***

Drs. Madhu Davies and Faiz Kermani

### ***What's in it for me: Why should I read this book?***

Appropriately designed and executed 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. With a little help from a friend, most people can get a grip on the topic in sufficient detail to understand in general terms what people are talking about. This book is that friend.

How we got to where we are is very important. 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.

Faiz and I 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. How does each group contribute to

the team's success? The chapters are designed to be jargon-lite but yet, detailed enough to provide the framework onto which you, the reader, can attach that jargon when you are good and ready.

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.

So why should you read this book? Because 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.

**Madhu Davies and Faiz Kermani**

April 2008