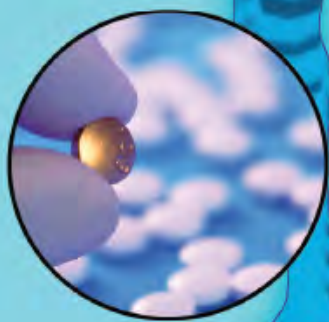


A quick guide to clinical trials · 2nd edition

Davies/Kermani



A quick guideTM to clinical trials

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

SECOND EDITION



EDITED BY:

**Drs. Madhu Davies and
Faiz Kermani**

SECOND EDITION

*A quick guide™ to
clinical trials*

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

EDITED BY:

Drs. Madhu Davies and Faiz Kermani

October 2016



BioPlan Associates, Inc.

Rockville, MD

BioPlan Associates, Inc.

2275 Research Blvd., Suite 500

Rockville, MD 20850 USA

301-921-5979

www.bioplanassociates.com

Copyright © 2016 by BioPlan Associates, Inc.

All rights reserved, including the right of reproduction in whole or in part in any form. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without the written permission of the publisher.

For information on special discounts or permissions, contact BioPlan Associates, Inc. at 301-921-5979, or info@bioplanassociates.com

Project Director: Donnie E. Gillespie

Production: E.S. Illustration & Design

Text and Cover Design: E.S. Illustration & Design

ISBN 978-1934-106-30-3

Preface to the Second Edition

We were delighted to hear that readers had found the first edition of this book helpful as they began to form an understanding of the clinical trials process. This second edition has been extensively revised and re-written to include additional topics and new subject matter experts to increase the breadth of the discussion of this fascinating discipline.

This is only possible because experts have given freely of their experience. We are both very grateful to the contributors who have set aside considerable time and thought to writing chapters to help you access and understand the fascinating world of clinical trials. Thank you.

Drs Madhu Davies and Faiz Kermani, October 2016



BOOK REVIEWS

"A Quick Guide to Clinical Trials is an excellent overview of the clinical trial process and drug development from an international perspective. It does an excellent job of carefully explaining the various roles and responsibilities of drug development professionals, and rather uniquely adds the patient perspective. If you want to know what goes on behind the scenes, and more importantly why, this is the book."

– Steven E. Linberg, PhD, Founder, S.E. Linberg Consulting, LLC;
Adjunct Graduate Faculty, Johns Hopkins University

"This book is a well-presented, quick reference guide covering a broad range of important and relevant clinical trial-related topics that can provide students and professionals new to industry studies with a simplified, easy-to-understand resource."

– Dr. Ernest A. Kopecky, VP, Clinical Development;
Head, Neuroscience, Collegium Pharmaceutical, Inc.

"This book provides many chapters of excellent information regarding clinical trials, and is a must-read for all persons involved in the area of clinical trials."

– Suzanne Sensabaugh, President and Principal Consultant, HartmannWillner

"An invaluable guide to navigate the complexities of clinical drug development."

– Leigh van Wyk, Director of Learning Strategy, Medical Education, Ogilvy Healthworld

"Having lead a Federal Agency with a 'science to service' mission, I found this book to be a straight forward and comprehensive guide to understanding the essential elements of clinical trials."

– Charles G. Curie, Principal, The Curie Group, LLC

"As clinical trials become more complex, this book still manages to keep the subject simple. If you are an investigator in academia conducting your own clinical trials, starting a career in the pharmaceutical industry, or one of the companies providing services to the pharmaceutical industry, this book is a must for you."

– Prof. Michael Davidson, Professor of Psychiatry, Sackler School of Medicine

"This book is a readable, comprehensive primer on clinical trials that conveys their basic fundamentals as well as their excitement and challenges."

– Dr. Larry Alphas, Therapeutic Area Leader, Psychiatry, Janssen

"In our globally connected world, clinical trials remain the nexus of scientific exchange within the medical science community. Davies and Kermani have updated this essential primer to include a global perspective to this complex, resource-intensive process."

– Jane Chin, Ph.D. Founder, Medical Science Liaison Institute

"You are in safe hands once you open this book. The updated edition takes a new starter or even seasoned clinical research professional through the "what to do and why" scenarios very comprehensively. The regulatory advice will help project teams to understand why they are being asked to perform certain tasks or why a protocol collects certain data that could be challenging. The chapter on Japan is highly recommended - as knowing where to start and how to make a trial work there can be so difficult to navigate. Also good to see the ePRO is included and updated, given how much the industry will lean on this in future."

– Sian Hingston, Project Management Professional, PPD

Contents

About the Contributorsix

Setting the scene

- Chapter 1:** **Introduction: What's in it for me: Why should I read this book?1**
 Drs Madhu Davies and Faiz Kermani, PhD
- Chapter 2:** **Why Do We Do Clinical Trials?.....5**
 Dr Graham Wylie
- Chapter 3:** **FDA and Clinical Drug Trials: A Short History29**
 Dr Suzanne Junod, PhD
- Chapter 4:** **Primer on Ethics in Clinical Research.....63**
 Dr Harris Dalrymple, PhD
- Chapter 5:** **The Business of Successful Drug Development.....83**
 Dr Todd Johnson, MD

Nuts and bolts

- Chapter 6:** **The Clinical Trials Process: Quality Management Systems93**
 Dr Julie Meeson, PhD
- Chapter 7:** **The Clinical Trials Process: Project Management.....115**
 Mrs. Joy Dummer
- Chapter 8:** **The Clinical Trials Process: Regulatory Affairs and Clinical Trials135**
 Dr Faiz Kermani, PhD and Dr Madhu Davies

Chapter 9:	The Clinical Trials Process: Study Monitoring.....	163
	Dr Ignazio Di Giovanna, PhD and Dr Gareth Hayes, PhD	
Chapter 10:	The Clinical Trials Process: Statistics.....	181
	Mrs Cathy O'Brien	
Chapter 11:	The Clinical Trials Process: What is Data Management?.....	197
	Mrs Lisa Nash	
Chapter 12:	The Clinical Trials Process: Technology in Clinical Trials	217
	Dr Bill Byrom, PhD	
Chapter 13:	The Clinical Trials Process: Clinical Trials and the role of Medical Writers	235
	Dr Lisa Chamberlain James, PhD and Dr Julia Forjanic Klapproth, PhD	
Chapter 14:	The Clinical Trials Process: Role of the Clinical Research Physician	249
	Dr Madhu Davies	
<hr/>		
	<i>Clinical Trials: Broadening the outlook</i>	
Chapter 15:	Clinical Trials and the Patient: Why Does a Patient Join a Clinical Trial?.....	261
	Mrs Elizabeth Langley	
Chapter 16:	Clinical Development Guide to Japan	273
	Dr Hajimu Morioka, PhD	

Chapter 17:	Clinical Trials in Resource-limited Settings	283
	Dr Faiz Kermani, PhD	
Chapter 18:	The Future of Clinical Trials	303
	Dr Faiz Kermani, PhD	
Glossary	315

Figures and Tables

Figure 5.1:	2012 Worldwide Active R&D Projects by Phase	84
Figure 5.2:	“Decision gates”	87
Figure 6.1:	Deming cycle	97
Figure 6.2:	Typical Quality Risk Management Process	101
Figure 6.3:	Example of an Organizational Chart	104
Figure 6.4:	Example of a Typical Controlled Document Hierarchy	107
Figure 8.1:	The Product Lifecycle	137
Figure 8.2:	Regulatory Affairs Is Vital for All Stages of the Lifecycle of a Medicine	159
Figure 10.1:	Cumulative Probability Plot for Height	183
Figure 10.2:	Example Pharmacokinetic Profile	185
Figure 10.3:	Phases of Clinical Research	188
Figure 11.1:	An Example of a Paper Data Management Process	200
Figure 11.2:	An Example of an Electronic Data Management Process, With Electronic Data Capture (EDC)	200
Figure 11.3:	Example Demography Screen on an Electronic Data Management System	201
Figure 11.4:	Example of a Paper Demography Page	202
Figure 11.5:	An Example of the MedDRA Hierarchy as Demonstrated with a PT of Headache	208
Figure 12.1:	Automated Supply Chain Management Using IVR/IWR	221
Figure 12.2:	Typical Workflow When Using an Electronic Data Capture System	225
Figure 12.3:	Medical Imaging Solutions in Clinical Trials	228
Figure 12.4:	Centralized Image Review	228
Figure 12.5:	Example of Data Quality Issues with a Simple Paper Diary	230

Figure 12.6:	Common ePRO Modalities	232
Figure 12.7:	A typical Smartphone ePRO Solution: TrialMax Touch® device displaying a numeric rating scale for pain rating	233
Figure 13.1:	Nomenclature for Study Reports.....	238
Figure 13.2:	The CTR Production Process Involving a Strategic Medical Writer	242
Figure 13.3:	The Role of the Medical Writer	244
Fig 18.1:	Estimated Number of Industry-Sponsored Clinical Trials in the U.S. by Phase in 2013.....	304
Fig 18.2:	Estimated Number of Trial Participants in Industry-Sponsored Clinical Trials in the U.S. by Phase in 2013.....	305
Fig 18.3:	Prevalence of Diabetes.....	306
Table 2.1:	Classification of Clinical Trials by Objective	17
Table 6.1:	Requirements of a QMS per ISO9001:20154 and Examples.....	99
Table 8.1:	The Regulatory Affairs Profession Summarized at Four Stages.....	138
Table 8.2:	ICH Discussion Topics.....	142
Table 8.3:	FDA Meetings.....	148
Table 8.4:	Routes for Authorizing Medicines in the EU.....	150
Table 8.5:	Overview of FDA’s Expedited Programs for Serious Conditions.....	157
Table 9.1:	Traditional Monitoring vs. Risk Based Monitoring	172
Table 9.2:	The Monitoring Visit.....	176
Table 17.1:	Project outline – Developing a Global Observatory for Health R&D	288
Table 18.1:	Potential Benefits and Risks of Involvement in a Clinical Trial.....	310

About the contributors

- * **Dr Bill Byrom, PhD, ICON plc.** As Senior Director within Product Innovation at ICON plc, focussing on harnessing new technologies within clinical trials, Dr Byrom worked within the pharmaceutical industry for over 25 years. He is an industry thought leader in the area of eClinical technologies and is the author of over 60 publications including a leading industry textbook on electronic Patient Reported Outcomes (ePRO). Dr Byrom is Industry Vice Director of the Critical Path Institute's ePRO Consortium and the eClinical Forum, and holds a PhD in disease simulation. He provides additional eClinical commentary via LinkedIn (<http://uk.linkedin.com/pub/bill-byrom/5/697/713>) and Twitter (@billbyrom).

- * **Dr Lisa Chamberlain James, Senior Partner and CEO, Trilogy Writing & Consulting GmbH.** Aside from management activities, Dr Chamberlain James also contributes to client projects, with extensive experience in a variety of documents, and with a special interest in drug safety and patient information. After receiving her PhD in Pathology, Dr. Chamberlain James began her medical writing career in Cambridge in 2000. Since then she has also been involved in the European Medical Writers Association (EMWA). Lisa is a member of the EMWA Educational Committee, a leader and assessor of EMWA workshops, a mentor of EMWA workshop leaders, has helped to produce the EMWA conference program from 2010 onwards, and holds an EMWA personal development certificate. Dr. Chamberlain James is also a member of The Organisation for Professionals in Regulatory Affairs (TOPRA) and the Pharmaceutical Information and Pharmacovigilance Association (PIPA), is chair of the EMWA PV Special Interest Group and Geoff Hall Scholarship Committee, and is a Fellow of the Royal Society of Medicine.

- * **Dr Harris W. Dalrymple, PhD (Med), PhD, (Law), Executive Director, Scientific Affairs, PRAHS.** After his academic career, Dr. Dalrymple spent nearly 25 years with a major pharmaceutical company followed by over a decade with two major contract research organizations, holding a variety of senior operational and managerial positions. His particular interest is in the involvement of vulnerable populations in research.

- * **Dr Madhu Davies MB, ChB, MRCP, FFPM, MBA.** Dr Madhu has over 20 years' experience with a range of pharmaceutical and biotechnology companies. She has supported the development and launch of a wide range of products in all the major markets and has been involved in the in-licensing and out-licensing of projects both in the large pharma and biotech setting. She is also a Non-Executive Director of a public sector organization, provides direction to the Postgraduate Course in Pharmaceutical Medicine (Cardiff University/British Association of Pharmaceutical Physicians) and is editor of "Pharmaceutical Physician" journal. She also co-edited the book "Patient Compliance: Sweetening the Pill" with Dr Faiz Kermani. Dr Madhu qualified in medicine from Birmingham University, she is a member of the Royal College of General Practitioners, a Fellow of the Faculty of Pharmaceutical Medicine and has an MBA from the Judge Business School, University of Cambridge.

- * **Joy Dummer, RGN (Hons), R.M., Senior Director of Project Delivery, PRA Health Sciences.** Ms. Dummer has 30 years' industry experience gained with several leading CROs. In previous roles she has been a Global Project Director, managing studies of all study phases across EU, North America and Asia Pacific. Therapeutic experience includes Oncology, CNS, Immunology, Infectious Disease, Women's Health and General medicine in adult and pediatric indications. Joy is also a Registered Nurse and State Registered Midwife. More recently she has held leadership positions in the CRO environment as Senior Director of Clinical Development, responsible for the project management team within a dedicated therapeutic Business unit.

- * **Dr Julia Forjanic Klapproth, PhD.** After receiving her PhD in Developmental Neurobiology, Dr Forjanic Klapproth started her career as a medical writer in 1997. In 2002, Julia co-founded Trilogy Writing & Consulting, a company specialized in providing medical writing of clinical regulatory documentation. For almost 20 years she has contributed her expertise in writing and coordinating all manner of regulatory documents. She has been President of the European Medical Writers Association (EMWA) twice and is an experienced trainer of medical writers, regularly running workshops for EMWA and pharmaceutical companies around the world.

- * **Dr Ignazio Di Giovanna, PhD.** Upon obtaining a PhD in Biophysics at Guys Hospital, based on development of non-invasive cardiovascular diagnosis techniques, Dr Di Giovanna joined the Pharmaceutical Industry in 1986 and has worked in the CRO field since 1990. Dr Ignazio Di Giovanna is owner and CEO of CCA Clinical Research, which has been established for over 25 years, a CRO which specializes in the management of phase I and II clinical studies. Dr Di Giovanna has been Chairman of the UK's Institute of Clinical Research (ICR) and also President of the Clinical Contract Research Association (CCRA). As a member of the Biotechnology & Pharmaceuticals Sector Advisory Group (BPSAG) he was active in advising the governmental body UKTI on trade and investment matters, with a view to increasing both for the UK economy. Dr Di Giovanna has also worked on a number of other industry related initiatives with the ABPI, NHS, R&D Forums and UKCRN; such as development of the mCTA, the national Costings Template and the Phase I insurance guidance. Dr Di Giovanna co-edited the 'Principles in Clinical Research', published in 2001 and in April 2004 was awarded an Honorary Fellowship by the ICR.

- * **Dr Gareth Hayes, PhD.** Dr Hayes is a dynamic trainer and has been a prevalent figure in the clinical research industry for over three decades, with over half of that in various monitoring and study management roles. Dr Hayes now runs Gareth Hayes Associates covering specialist training needs in addition to mandatory Good Clinical Practices. Professional mentoring is at the heart of Dr Hayes's purposeful curricula and includes career development programmes for all roles involved in research. Dr Hayes has latterly joined the Editorial Steering Committee of the new online Journal of Clinical Research & GCP. As well as delivering his own material Dr Hayes has also trained on behalf of Pharmaschool Ltd and the Institute of Clinical Research and in 2014 passed the Verified Assessor & Accreditation Programmes with the International Academy of Clinical Research.

- * **Dr Todd Johnson, MD, MBA, CEO, CytoVas.** Dr Johnson is a thought-leader in precision medicine and drug development. He is currently CEO of CytoVas, a diagnostics company that is using proprietary data mining tools to discover new biomarkers for disease progression and treatment response. Prior to CytoVas, Dr Johnson's experiences range from consulting at McKinsey & Company, to leading the turnaround

of Abbott Lab's pharma pipeline, enabling the creation of AbbVie. Dr Johnson holds a Bachelor of Arts from Penn, an MBA from its Wharton School, and an MD from Penn Med.

* **Dr Suzanne W. Junod.** Dr Junod received her M.A. and PhD. from Emory University in the history of medicine. She came to the FDA as a historian in 1984. In 1994-5, she served as FDA liaison and historical consultant for President Clinton's Advisory Committee on Human Radiation Experiments (ACHRE). Dr Junod is on the Editorial Board of the Journal of the History of Medicine and Allied Sciences and has written the "History Corner" -- a bimonthly column for the Food and Drug Law Institute's Update publication for the past decade. Her publications are wide-ranging in the history of medicine and public health, including women's health, history of food additive regulation, as well as food and drug legal, scientific, and regulatory issues. She has received several professional awards for her writing.

* **Dr Faiz Kermani.** Dr Kermani's background is in medical research and the pharmaceutical sector, where he has held scientific, regulatory and commercial roles in Europe and the US. He has practical experience of launching and publicizing the work of non-profit organizations, especially in the field of healthcare and education. He has also published a number of articles on neglected diseases and disparities in global healthcare. He serves on the board of the World Medical Fund (WMF), a medical charity working in Africa. WMF's main programs are in central Malawi and are treating more than 25,000 sick children every year. Dr Kermani has a PhD in Immunopharmacology from St. Thomas' Hospital, London and a First Class Honors degree in Pharmacology with Toxicology from King's College, London.

* **Mrs. Elizabeth Langley.** Mrs. Langley graduated from Surrey University in 1978 with a BSc (Hons) in Biochemistry (Medical) training to be a Clinical Chemist. Rather than pursue a hospital based role she joined the pharmaceutical industry working in a variety of roles including that of CRA, a New Product Development scientist, a regional sales team leader and marketing director. Since 2000 she has not only run her own company (LHA) but has also provided management services to the British Association of Pharmaceutical Physicians (BrAPP) which celebrates its 60th year in 2017. In 2014, fulfilling a long-term career ambition, BrAPP took over the future development, coordination

and running of the internationally respected PostGraduate Course in Pharmaceutical Medicine and working with Cardiff University and Dr Madhu Davies, she has seen improved satisfaction from delegates and a sniff of improving academic results.

- * **Dr Julie Meeson, PhD, J3i Limited.** Dr Meeson is a Quality Assurance professional experienced in setting up Quality Management Systems for commercial organizations (Pharmaceutical, Biotechnology and Contract Research Organizations) as well as for research sites. She also assists organizations prepare for FDA and European regulatory inspections.

- * **Dr Hajimu (Jim) Morioka** serves as a consultant for a variety of businesses relating to biotechnology with TechNova Consulting Japan. He is also Team Leader, ABS Task Force Team for Academia under the instruction of the Ministry of Education, Culture, Sports, Science and Technology (MEXT). The ABS was set up to promote academic research using genetic resources at universities and institutions, enabling compliance with the Nagoya Protocol, a supplementary agreement to the Convention on Biological Diversity. The Nagoya Protocol covers areas such as access to genetic resources, benefit-sharing and compliance. Prior to this role Dr Morioka worked for 37 years in industry positions, conducting pharmaceutical R&D and licensing activities, strategic R&D planning and managing intellectual property on behalf of companies. Dr Morioka also served as a director of Japan Biological Informatics Consortium for medicinal development. Dr Morioka graduated in microbiology and molecular biology from Kyoto University in 1975 and earned a PhD from the same university in 1988. He also studied molecular biology at the National Institutes of Health in the US. He now also serves as a consultant for a variety of businesses relating to biotechnology with TechNova Consulting Japan.

- * **Lisa Nash BSc PGCE, GSK.** Ms. Nash graduated from University College London with a BSc (Hons) in Chemistry in 1993 and went on to obtain a Post Graduate Certificate in Education from Homerton College Cambridge in 1994. After 3 years of teaching she embarked on a new career in Data Management at former SmithKline Beecham which became GlaxoSmithKline. Since 1997 until the present Ms. Nash has worked in various data management roles with over a decade of this supporting late phase tropical disease trials in the developing world. More recently she has been working in the early phase arena and overseeing data strategy for GlaxoSmithKline's clinical pharmacology unit.

- * **Mrs. Cathy O'Brien, MSc.** Mrs. O'Brien is a chartered statistician with over 25 years in the pharmaceutical industry. She graduated from London University in 1985 with a degree in Biology and Mathematics and started work as a statistician in horticultural research before moving into clinical trials. She obtained an MSc in Medical Statistics from Leicester University. Having worked for both a CRO and a pharmaceutical company, she is currently working as a statistical consultant through her own business.

- * **Dr Graham Wylie, BSc MB BS, CEO, Medical Research Network.** Dr Wylie is the CEO of the Medical Research Network, a business running clinical trial activities in the patient's own home, for 10 years. Dr Wylie's career started with 10 years at Pfizer, initially in Project Management and subsequently in systems and process re-engineering. After 5 years at Parexel as Medical Director for Northern Europe then VP Sales for Clinical Research Services, he joined Healthcare at Home in 2005, leading the management buyout of MRN in 2006.

Chapter 1

Introduction

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

Drs. Madhu Davies and Faiz Kermani, PhD

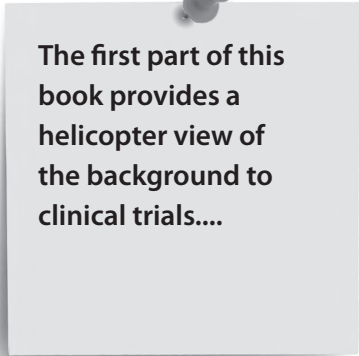
What's in it for me: Why should I read this book?

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 have a vocabulary and jargon all of their 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.

In response to feedback on the first edition, we have re-ordered the topics and added additional subject matter; how we got to where we are being very important. The first part of this book provides a helicopter view of the background to clinical trials with Chapter 1 providing a brief history of the clinical trial as an orientation aid, and Chapter 2 explaining why we do what we do as a broad structure into which the later 'process' chapters will fit. The third chapter reviews the history of a major regulatory body, the United States Food and Drug Administration and the considerations that led to the setting up of that body flow nicely into the 'Primer' on research ethics (Chapter 4). Complementing these chapters is the commercial perspective: the imperative for moving forward.

Armed with these 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. How does each group contribute to the team's success? In order to provide links between chapters there is some intentional overlap. This is particularly noticeable for discussions about ethics which demonstrates just how core these considerations are to each of our contributors and to clinical research in general.



The first part of this book provides a helicopter view of the background to clinical trials....

In a world with a rich and detailed language and vocabulary, the chapters are designed to be relatively 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. Words are used interchangeably e.g., ‘drug’ and ‘medicine’; ‘study’ and ‘trial’. The principles apply across the development of medicines, devices and combinations although the specifics of the regulatory frameworks will naturally differ.

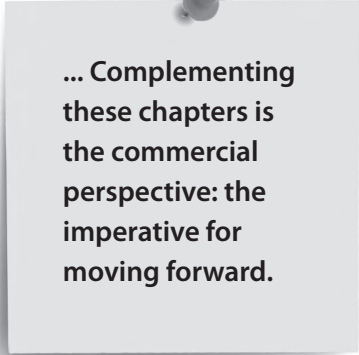
In addition, we felt it was critical to acknowledge the role of the patient and to try to understand their perspective because without their participation no clinical trial would proceed. Frequently, it is the enthusiasm and dedication of patients that keep clinical trials on track. There is currently 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 15 helps fill this ‘gap’ as it is written by someone who has both worked on clinical trials as a clinical research professional and also participated in an oncology trial as a patient.

Thinking more widely, the next two chapters discuss the nuances of clinical development in Japan and by contrast in resource-poor settings – both areas of increasing interest and activity.

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



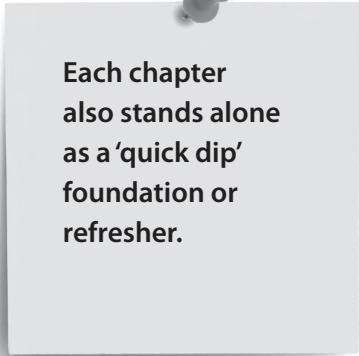
... Complementing these chapters is the commercial perspective: the imperative for moving forward.

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 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

October 2016



**Each chapter
also stands alone
as a 'quick dip'
foundation or
refresher.**

TO ORDER THIS BOOK CONTACT THE PUBLISHER:

**BioPlan Associates, Inc.
2275 Research Blvd, Suite 500
Rockville, MD 20850
+1 301 921 5979**

**www.bioplanassociates.com
orders@bioplanassociates.com**

"A Quick Guide to Clinical Trials is an excellent overview of the clinical trial process and drug development from an international perspective. It does an excellent job of carefully explaining the various roles and responsibilities of drug development professionals, and rather uniquely adds the patient perspective. If you want to know what goes on behind the scenes, and more importantly why, this is the book."

– Steven E. Linberg, PhD, Founder, S.E. Linberg Consulting, LLC;
Adjunct Graduate Faculty, Johns Hopkins University

"This book is a well-presented, quick reference guide covering a broad range of important and relevant clinical trial-related topics that can provide students and professionals new to industry studies with a simplified, easy-to-understand resource."

– Dr. Ernest A. Kopecky, VP, Clinical Development; Head, Neuroscience,
Collegium Pharmaceutical, Inc.

"This book provides many chapters of excellent information regarding clinical trials, and is a must-read for all persons involved in the area of clinical trials."

– Suzanne Sensabaugh, President and Principal Consultant, HartmannWillner

"An invaluable guide to navigate the complexities of clinical drug development."

– Leigh van Wyk, Director of Learning Strategy, Medical Education, Ogilvy Healthworld

"Having lead a Federal Agency with a 'science to service' mission, I found this book to be a straight forward and comprehensive guide to understanding the essential elements of clinical trials."

– Charles G. Curie, Principal, The Curie Group, LLC



Dr Madhu Davies MB ChB

MRCGP FFPM MBA. Dr Madhu has over 20 years' experience with a range of pharmaceutical and biotechnology companies. She has supported the development and launch of a wide range of products in all the major markets and has been involved in the in-licensing and out-

licensing of projects both in the large pharma and biotech setting. She is also a Non-Executive Director of a public sector organization, provides direction to the Postgraduate Course in Pharmaceutical Medicine (Cardiff University/British Association of Pharmaceutical Physicians) and is editor of "Pharmaceutical Physician" journal. She also co-edited the book "Patient Compliance: Sweetening the Pill" with Dr Faiz Kermani. Dr Madhu qualified in medicine from Birmingham University, she is a member of the Royal College of General Practitioners, a Fellow of the Faculty of Pharmaceutical Medicine and has an MBA from the Judge Business School, University of Cambridge.



Dr Faiz Kermani. Dr

Kermani's background is in medical research and the pharmaceutical sector, where he has held scientific, regulatory and commercial roles in Europe and the US. He has practical experience of launching and publicizing the work of non-profit organizations, especially in the field of healthcare and

education. He has also published a number of articles on neglected diseases and disparities in global healthcare. He serves on the board of the World Medical Fund (WMF), a medical charity working in Africa. WMF's main programs are in central Malawi and are treating more than 25,000 sick children every year. Dr Kermani has a PhD in Immunopharmacology from St. Thomas' Hospital, London and a First Class Honors degree in Pharmacology with Toxicology from King's College, London.

