



New! Clinical Trials Textbook

Chapter End Summaries, Discussion Questions, Teachers' Guide, and more! **Review Copies Available to Educators**

"A Quick Guide to Clinical Trials", 2nd ed. allows readers, both academic and professional, to get a firm grip on the topic, with just enough detail to ensure a comprehensive understanding. This 2nd edition, edited and written by Dr. Madhu Davies and Dr. Faiz Kermani, has been extensively revised to include additional topics and new subject matter experts to increase the breadth of discussion of this fascinating discipline. Each chapter stands alone as a 'quick dip' foundation or refresher.

Chapters are written by industry experts, carefully chosen for their abilities to clarify complex topics and make them interesting for everyone. Clinical trials that are well designed and appropriately executed are at the heart of the successful development of all new medicines. This edition continues to demystify the topic in an exceptionally reader-friendly, yet authoritative format.

Readers receive chapter end summaries, and discussion questions; those already in the field will receive updated, easy-to-read expert content. **Table of Contents Include: Setting the Scene, Nuts and Bolts of the Clinical Trial Process, and Broadening the Outlook!**

Your go-to guide for clinical trials!

"...an excellent overview of the clinical trial process and drug development from an international perspective."—Steven E. Linberg, PhD, Adjunct Graduate Faculty, Johns Hopkins University; Founder, S.E. Linberg Consulting, LLC.

"This book is a well-presented, quick reference guide covering a broad range of important and relevant clinical trial-related topics..." —Dr. Ernest A. Kopecky, VP, Clinical Development; Head, Neuroscience, Collegium Pharmaceutical, Inc.

About the Authors and Contributors

Dr Bill Byrom, PhD, Sr. Dir ICON plc
New Clinical Trials Technologies

Dr Lisa Chamberlain James, Sr. Partner / CEO
Trilogy Writing & Consulting GmbH

Dr Madhu Davies MB, ChB, MRCGP, FFPM, MBA

Joy Dummer, RGN (Hons), R.M., Sr.
Dir Project Delivery, PRA Health Sciences

Dr Julia Forjanic Klaproth, PhD.
Co-founder Trilogy Writing & Consulting

Dr Ignazio Di Giovanna, PhD.
Owner and CEO of CCA Clinical Research

Dr Gareth Hayes, PhD.
Owner Gareth Hayes Associates
Specialist Training

Dr Todd Johnson, MD, MBA, CEO
CytoVas diagnostics company

Dr Suzanne W. Junod,
US FDA, historian, FDA liaison and historical consultant

Dr Faiz Kermani,
Board of the World Medical Fund (WMF)

Mrs. Elizabeth Langley, CEO LHA

Dr Julie Meeson, PhD,
J3i Limited, Quality Assurance

Dr Hajimu (Jim) Morioka
TechNova Consulting Japan

Lisa Nash BSc PGCE
GlaxoSmithKline, Clinical Pharmacology
Unit data strategy

Mrs. Cathy O'Brien, MSc.
Chartered statistician

Dr Graham Wylie, Bsc MB BS, CEO
Medical Research Network

Edited by Drs. Madhu Davies and Faiz Kermani

\$95 plus shipping and handling
ORDER ONLINE HERE >

ISBN 978-1934-106-30-3
<http://bioplanassociates.com/qg-clinical-trials/>



Table of Contents

SETTING THE SCENE

Chapter 1: Introduction

Drs Madhu Davies, Faiz Kermani, PhD

Chapter 2: Why Do We Do Clinical Trials?

Dr Graham Wylie

Chapter 3: FDA and Clinical Drug Trials

Dr Suzanne Junod, PhD

Chapter 4: Primer on Ethics in Clinical Research

Dr Harris Dalrymple, PhD

Chapter 5: Business of Successful Drug Development

Dr Todd Johnson, MD

NUTS AND BOLTS- THE CLINICAL TRIALS PROCESS

Chapter 6: Quality Management Systems

Dr Julie Meeson, PhD

Chapter 7: Project Management

Mrs. Joy Dummer

Chapter 8: Regulatory Affairs & Clinical Trials

Drs Kermani and Davies

Chapter 9: Study Monitoring

Dr Di Giovanna, PhD and Dr Hayes, PhD

Chapter 10: Statistics

Mrs Cathy O'Brien

Chapter 11: What is Data Management?

Mrs Lisa Nash

Chapter 12: Technology in Clinical Trials

Dr Bill Byrom, PhD

Chapter 13: Clinical Trials and the role of Medical Writers

Dr Lisa Chamberlain James, PhD and Dr Julia Forjanic Klapproth, PhD

Chapter 14: Role of the clinical research physician

Dr Madhu Davies

CLINICAL TRIALS: BROADENING THE OUTLOOK

Chapter 15: Clinical Trials and the Patient: Why join?

Mrs Elizabeth Langley

Chapter 16: Clinical Development Guide to Japan

Dr Hajimu Morioka, PhD

Chapter 17: Clinical Trials in Resource-limited Settings

Dr F. Kermani, PhD

Chapter 18: The Future of Clinical Trials

Dr Faiz Kermani, PhD

More Reviews and Recommendations for A Quick Guide to Clinical Trials, 2nd Edition

ISBN 978-1934-106-30-3

<http://bioplanassociates.com/qg-clinical-trials/>

"A Quick Guide to Clinical Trials is an excellent overview of the clinical trial process and drug development from an international perspective." – **Steven E. Linberg, PhD, Adjunct Graduate Faculty, Johns Hopkins University; Founder, S.E. Linberg Consulting, LLC.**

"This book is a well-presented, quick reference guide covering a broad range of important and relevant clinical trial-related topics..." – **Dr. Ernest A. Kopecky, VP, Clinical Development; Head, Neuroscience, Collegium Pharmaceutical, Inc.**

"Clinical trials are the single most resource-intensive investment in bringing a drug to market. Davies and Kermani have created a primer that should be essential reading for any healthcare professional and life scientist who want to understand this complex, billion-dollar process." – **Jane Chin, Ph.D. President, Medical Science Liaison Institute**

"This book provides a broad overview of the complex issues involved in the design, conduct and oversight of clinical trials. The authors bring a 'hands-on' expertise and diversity of perspectives to the book. Clearly and simply written, the book will be especially useful for readers new to clinical trials regardless of their role, or for experienced readers who want to refresh their knowledge." – **Robert "Skip" Nelson, MD PhD, Pediatric Ethicist, Office of Pediatric Therapeutics, US Food and Drug Administration**

"As a job recruiter to this industry, I strongly urge each and every candidate considering a career in clinical research to read this book. They will have an advantage over others." – **Austen Yapp, Founder & Director, Jobs. Lead Discovery Ltd.**

"An excellent resource. Chapters 5 and 6 will be invaluable for new starters working in pharma or contract research. Given the current surge in recruitment, this may assist with the challenge of training to GCP standards. Chapter 11 on technology will explain the rise of electronic data solutions." – **Sian Hingston, Head of Clinical Resourcing, Global Clinical Operations Europe, GSK**

"This book covers the bases for anyone interested in clinical trials." – **Professor John Staniforth, CSO, PharmaKodex Ltd, UK**

"An invaluable guide to navigate the complexities of clinical drug development." – **Leigh van Wyk, Director of Learning Strategy, Medical Education, Ogilvy Healthworld**

"Having led 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 providing services, 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**

"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." – **Sian Hingston, Project Management Professional, PPD**

GLOSSARY

330 pages, 18 Chapters

Every chapter includes Summary

Chapter Key Ideas and

Discussion Questions

Instructors' guide available

ORDER ONLINE HERE >

[http://bioplanassociates.com/
qg-clinical-trials](http://bioplanassociates.com/qg-clinical-trials)

