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"A Quick Guide to Clinical Trials, 2nd Edition"

By Madhu Davies and Faiz Kermani, editors, 2016, 327 pages, BioPlan Associates, Inc., $95.00

Review by Norman M. Goldfarb

"A Quick Guide to Clinical Trials, 2nd Edition," unlike most other introductory texts, which focus on the investigative site, provides basic information for study sponsors. The scope of the book is unusually broad for a clinical research primer: from the history of clinical research, to study monitoring, to data management, to medical writing. This book would be a good primer for the Board of Directors of a biotechnology company.

The book includes a nice summary of the different types of clinical studies:

- First in Man – the first time a human is exposed to the product
- Pharmacokinetic – literally, assessing the movement of the product through the body
- Proof of concept – setting up a simple test for the effect you are looking for, for example giving a volunteer a pain stimulus and then seeing if this is reduced by a drug you hope is an analgesic; it is a model of the illness, not the illness itself
- Mechanism of action – looking for the pharmacological effect of a product, e.g., receptor blockade
- Dose ranging – exploring the doses required in patients for maximum effect with minimum side effects
- Large scale exposure –large trials in patient populations looking at safety and efficacy in detail
- Expanded access – studies designed to increase the exposure of patients to a product at the end of a development program as the sponsor waits for approval to launch onto the market
- Peri-launch – trials around the launch of the drug to maximize its commercial impact when launched
- Regulatory commitment – a trial required by the licensing authority as part of its approval of the license to market the product
- Market support – trials to meet the needs of the prescribing physicians (usually experts in their field) to understand the product better

The book includes 18 chapters by 17 contributors:

- Introduction: What's In It For Me: Why Should I Read This Book?
- Why Do We Do Clinical Trials?
- FDA and Clinical Drug Trials: A Short History
- Primer on Ethics in Clinical Research
- The Business of Successful Drug Development
- The Clinical Trials Process: Quality Management Systems
- The Clinical Trials Process: Project Management
- The Clinical Trials Process: Regulatory Affairs and Clinical Trials
- The Clinical Trials Process: Study Monitoring
- The Clinical Trials Process: Statistics

- The Clinical Trials Process: What is Data Management?
- The Clinical Trials Process: Technology in Clinical Trials
- The Clinical Trials Process: Clinical Trials and the Role of Medical Writers
- The Clinical Trials Process: Role of the Clinical Research Physician
- Clinical Trials and the Patient: Why Does a Patient Join a Clinical Trial?
- Clinical Development Guide
- Clinical Trials in Resource-Limited Settings
- The Future of Clinical Trials

Reviewer

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