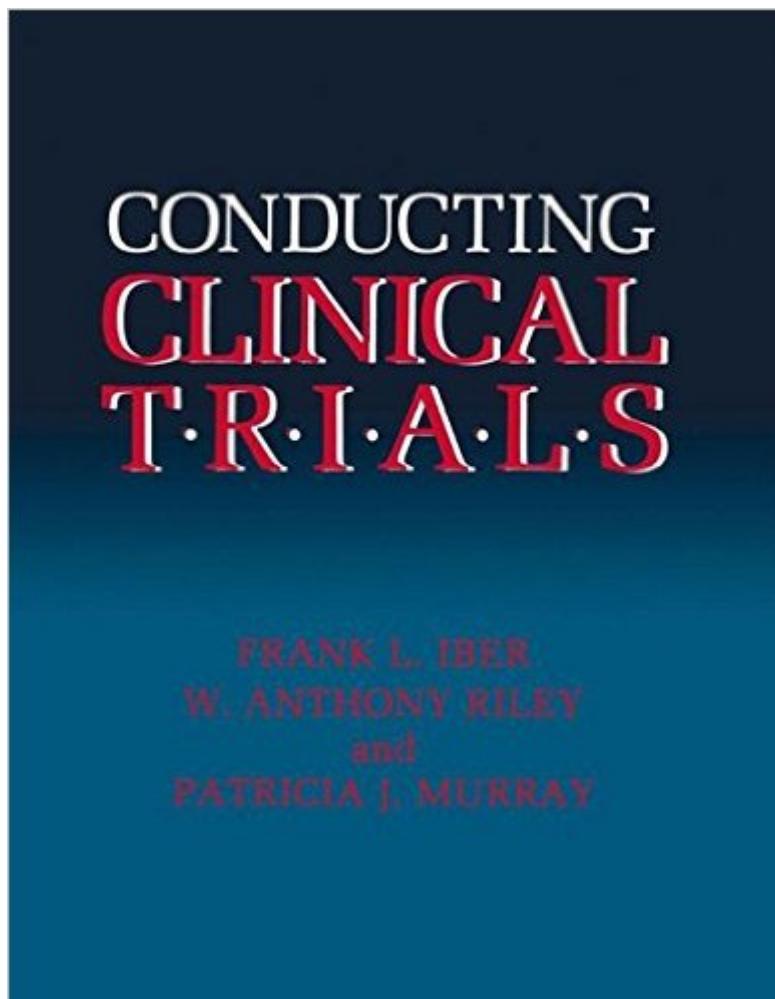


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Conducting Clinical Trials



Synopsis

A few years ago, two of us joined our senior colleague at Pharma- Kinetics Laboratories, a newly public contract research firm just under- taking a major expansion into the clinical trials market. The company's unique concept of clinical research held great promise and had suc- cessfully endured many of the fits and starts characteristic of entrepre- neurial organizations. With a staff of highly enthusiastic, albeit inex- perient, field personnel located in 30-odd cities around the country, we found ourselves off and running with several critical research pro- grams for major pharmaceutical manufacturers. Our excitement with the innovation was tempered with the reality of staffing and bearing responsibility for more than 30 field offices and 300 new staff persons, more than half of whom had no previous experience in the pharma- ceutical industry. In the ensuing few years, we explored by trial and error many workable and unworkable patterns of training! delegation, data collec- tion, and auditing. The ideas expressed in this book benefited greatly from that experience and from the willingness of our co-workers and clients to share insights and problems. During those years, we also sought guidance from the works available on the clinical trials field. Although we found numerous references on research ethics, little guid- ance was available on the practical aspects of conducting a clinical trial.

Book Information

Hardcover: 366 pages

Publisher: Springer; 1987 edition (September 30, 1987)

Language: English

ISBN-10: 0306426269

ISBN-13: 978-0306426261

Product Dimensions: 6.4 x 1 x 9.3 inches

Shipping Weight: 1.4 pounds

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Best Sellers Rank: #2,752,750 in Books (See Top 100 in Books) #116 in Books > Medical Books > Pharmacology > Clinical #1815 in Books > Medical Books > Research #2185 in Books > Textbooks > Medicine & Health Sciences > Medicine > Basic Sciences > Pharmacology

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