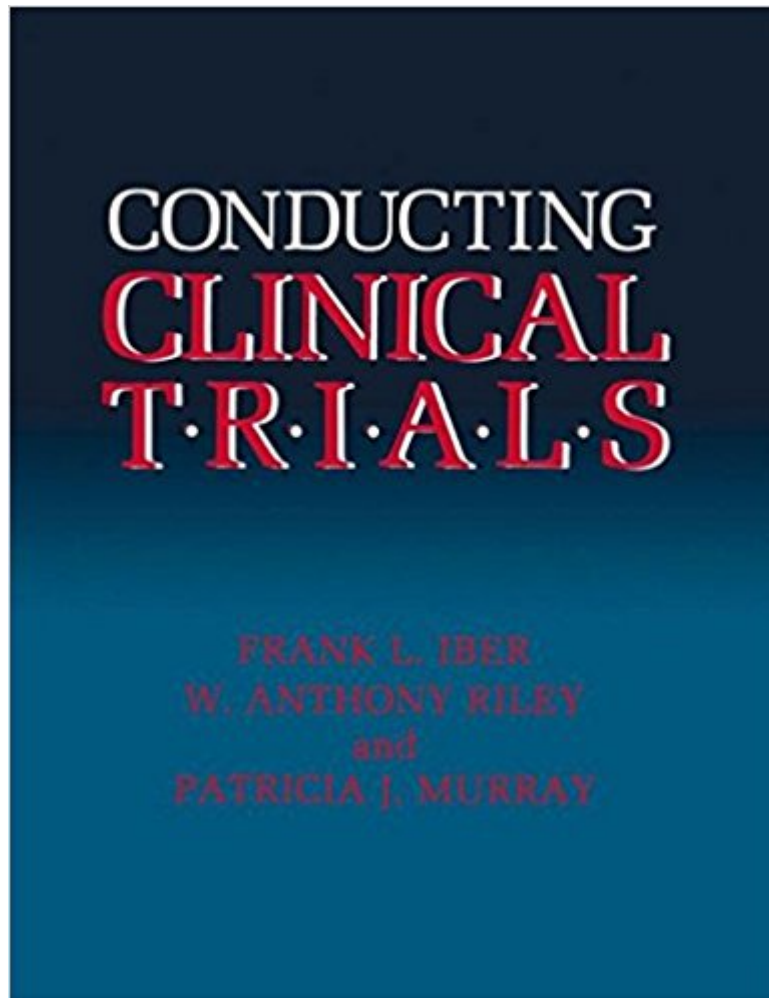




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# Conducting Clinical Trials



## 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 successfully endured many of the fits and starts characteristic of entrepreneurial organizations. With a staff of highly enthusiastic, albeit inexperienced, field personnel located in 30-odd cities around the country, we found ourselves off and running with several critical research programs 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 pharmaceutical industry. In the ensuing few years, we explored by trial and error many workable and unworkable patterns of training, delegation, data collection, 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 guidance was available on the practical aspects of conducting a clinical trial.

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