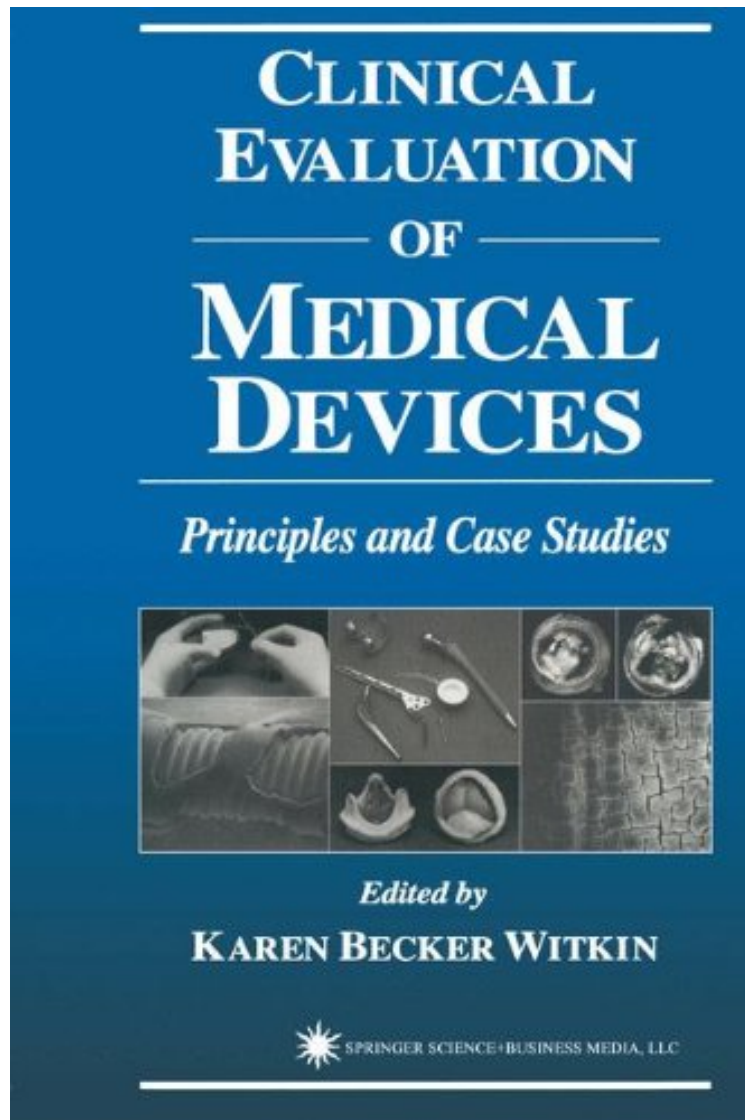


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Clinical Evaluation of Medical Devices: Principles and Case Studies

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The world is changing rapidly, and nowhere is this more apparent than in medicine. The standards are rapidly rising in the field of medical device trials. A few years ago, device developers would look askance if one told them that medical

device trials and drug trials should have the same standards. Today, such a statement does not seem as outrageous, although there is still a large gap in the design of trials and number of trials conducted for medical device and drug development programs. More than 20 years after the enactment of the US Medical Device Amendments, we can see that they served as an impetus to raise clinical trial standards for devices. Whether the data to establish the safety and efficacy of a device come from one, two, or even more clinical trials is less important in evaluating the device than whether the data are medically and scientifically supportive of its safety and efficacy. Having at least two separate studies, and at least two sites confirm results, adds a great deal of scientific credibility and support to a conclusion of safety and efficacy, even though a confirmatory trial is not yet a regulatory requirement in most countries.

From the Back Cover
In *Clinical Evaluation of Medical Devices* Karen Becker Witkin and her distinguished colleagues summarize for the first time the key principles and approaches to be used in medical device clinical trials, and then demonstrate the implementation of these principles in a revealing series of detailed, real-world case studies. Building on the techniques used in clinical trials of pharmaceuticals, these highly experienced contributors show how to design and evaluate clinical trials of medical devices, as well as how best to collect data that is acceptable to the FDA. They also explain when, why, and how clinical research fits into the development and marketing of new product concepts and spell out international regulatory requirements for research and registration of medical devices. Nine detailed case studies illustrate the wide range of study designs that have been successfully applied to many different research problems and a variety of therapeutic or diagnostic products. *Clinical Evaluation of Medical Devices* will not only play a key role in establishing clinical trials of medical devices as a rigorous science, but also provide today's only source of case-study-based practical information on how clinical study design principles are best tailored to the successful evaluation of novel medical devices.