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 stan dards. Today, such a statement does not seem as outrageous, although there is still a large gap in the design of trials and number oftrials 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 support ive 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.

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