

In 2010, more than 80,000 clinical trials were conducted globally, on over 5,600 drugs, biologics and medical devices. Most of these trials were sponsored by industry or government, and together they focused on almost every disease or medical condition you could name. The entities that finance these trials are called “sponsors,” working toward the goal of regulatory approval for marketing these products.

Clinical research is a venture with multiple partners. The sponsors generally plan, initiate and finance the trial, and own the compounds or devices being developed. The physicians and their staffs conduct the clinical investigations, and their patients and human subjects participate in the trials. There are also ethics committees and Institutional Review Boards (IRBs) that must approve the studies before they can begin and then keep watch over the trials to protect the patients. Then there are the regulatory bodies (FDA and HHS in the United States) that regulate research and make the final decision about whether or not to approve the product for marketing.

This book specifically looks at clinical trials, those research studies that involve humans in the testing of potential new products. Trials are conducted at thousands of sites across the country and around the world, including hospitals, academic medical centers, clinics, clinical research centers and physicians’ offices. The book is written particularly to help and educate Clinical Research Associates (CRAs), the sponsor representatives who monitor and oversee these studies for a sponsor.

Throughout the book we will look at all facets of clinical trials including regulatory matters; partners in research; the planning, structure and organization required for trials; how trials are handled and monitored, and more. We have included key points to remember in each chapter, some real-life scenarios, and exercises to help test your recall.

Whether you are a CRA or another partner in conducting clinical trials, or you simply have an interest in learning about this field, you will find this book both informative and useful.

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