

Clinical research is a complicated undertaking, 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 investigations, and their patients and trial subjects participate in the trials. There are also ethics committees (IRBs) that must approve the studies before they can begin and then must keep watch over the trials to protect the human subjects. Last, but not least, are the regulatory bodies (FDA and HHS in the United States) that regulate the research and make the final decision about whether or not the product is approved for marketing.

This book looks specifically 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. This book was written particularly to help and educate Clinical Research Coordinators (CRCs), the people who work in conjunction with clinical investigators at research sites. CRCs are the main liaison between the investigators and the study subjects, and between the site and the sponsor; they also handle a great deal of the study activity at clinical sites.

Throughout the book we will look at all facets of clinical trials, including regulatory matters; the partners in research; the planning, structure and organization that go into trials; how trials are conducted and managed, and much more. We have included key takeaways at the end of each chapter, as well as some real-life "case studies."

Whether you are a CRC or another partner in clinical trials, or just have an interest in learning about this activity, we hope you will find the book both informative and useful.

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