



Oncology Clinical Trials: Successful Design, Conduct and Analysis

Richard Schilsky MD

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Clinical trials are the engine of progress in the development of new drugs and devices for the detection, monitoring, prevention and treatment of cancer. A well conceived, carefully designed and efficiently conducted clinical trial can produce results that change clinical practice overnight, deliver new oncology drugs and diagnostics to the marketplace, and expand the horizon of contemporary thinking about cancer biology. A poorly done trial does little to advance the field or guide clinical practice, consumes precious clinical and financial resources and challenges the validity of the ethical contract between investigators and the volunteers who willingly give their time and effort to benefit future patients. With chapters written by oncologists, researchers, biostatisticians, clinical research administrators, and industry and FDA representatives, *Oncology Clinical Trials*, provides a comprehensive guide for both early-career and senior oncology investigators into the successful design, conduct and analysis of an oncology clinical trial.

Oncology Clinical Trials covers how to formulate a study question, selecting a study population, study design of Phase I, II, and III trials, toxicity monitoring, data analysis and reporting, use of genomics, cost-effectiveness analysis, systemic review and meta-analysis, and many other issues. Many examples of real-life flaws in clinical trials that have been reported in the literature are included throughout. The book discusses clinical trials from start to finish focusing on real-life examples in the development, design and analysis of clinical trials.

***Oncology Clinical Trials* features:**

- A systematic guide to all aspects of the design, conduct, analysis, and reporting of clinical trials in oncology
- Contributions from oncologists, researchers, biostatisticians, clinical research administrators, and industry and FDA representatives
- Hot topics in oncology trials including multi-arm trials, meta-analysis and adaptive design, use of genomics, and cost-effectiveness analysis
- Real-life examples from reported clinical trials included throughout

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