



A Concise Guide to Clinical Trials

J. Rick Turner PhD

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Biopharmaceutical drugs improve the health and well-being of people across the globe on a scale that is unrivaled by any other medical intervention. Before these drugs can be prescribed for patients by their doctors, they have to be approved for marketing by a regulatory agency. To gain marketing approval, drugs must go through an extremely rigorous process that investigates their safety and efficacy, the process of New Drug Development. The last stage of this long, complex, and expensive process involves conducting clinical trials, the topic of this book. Successfully conducting clinical trials requires the interdisciplinary collaboration of individuals from many clinical and scientific disciplines and areas of operational expertise. These include medicine, information technology, ethics and law, statistics, clinical trial operations, data collection and management, regulatory science, and medical writing, to name just a few. Central aspects of conducting clinical trials are discussed in the following chapters, with the goals of making specialists from each of these areas aware of the contributions of their colleagues, and helping readers to appreciate that everyone involved in clinical research is working side-by-side toward a common goal--improving the health, well-being, and longevity of millions of patients around the globe.

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