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Intelligent Drug Development: Trials And Errors In Clinical Research



Synopsis

Clinical research is heavily regulated and involves coordination of numerous pharmaceutical-related disciplines. Each individual trial involves contractual, regulatory, and ethics approval at each site and in each country. Clinical trials have become so complex and government requirements so stringent that researchers often approach trials too cautiously, convinced that the process is bound to be insurmountably complicated and riddled with roadblocks. A step back is needed, an objective examination of the drug development process as a whole, and recommendations made for streamlining the process at all stages. With *Intelligent Drug Development*, Michael Tansey systematically addresses the key elements that affect the quality, timeliness, and cost-effectiveness of the drug-development process, and identifies steps that can be adjusted and made more efficient. Tansey uses his own experiences conducting clinical trials to create a guide that provides flexible, adaptable ways of implementing the necessary processes of development. Moreover, the processes described in the book are not dependent either on a particular company structure or on any specific technology; thus, Tansey's approach can be implemented at any company, regardless of size. The book includes specific examples that illustrate some of the ways in which the principles can be applied, as well as suggestions for providing a better context in which the changes can be implemented. The protocols for drug development and clinical research have grown increasingly complex in recent years, making *Intelligent Drug Development* a needed examination of the pharmaceutical process.

Book Information

Hardcover: 240 pages

Publisher: Oxford University Press; 1 edition (May 14, 2014)

Language: English

ISBN-10: 0199974586

ISBN-13: 978-0199974580

Product Dimensions: 9.3 x 0.9 x 6.3 inches

Shipping Weight: 1.1 pounds (View shipping rates and policies)

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