Clinical Development: Strategic Pre-Clinical and Regulatory Issues

Clinical Development: Strategic, Pre-Clinical, and Regulatory Issues by Janice Steiner

★★★★★ 5 out of 5

Language	: English
File size	: 5234 KB
Text-to-Speech	: Enabled
Screen Reader	: Supported
Enhanced typesetting	: Enabled
Word Wise	: Enabled
Print length	: 238 pages

Clinical development is the process of evaluating the safety and efficacy of a new drug or device in humans. It is a complex and expensive process, and it can take many years to complete. However, clinical development is essential for bringing new treatments to market and improving the lives of patients.

This book provides a comprehensive overview of the clinical development process, from pre-clinical research to regulatory approval. It covers all aspects of clinical development, including study design, data management, and statistical analysis. The book is written by a team of experts in clinical development, and it is packed with practical advice and insights.

Pre-Clinical Research

Pre-clinical research is the first step in the clinical development process. It is conducted in the laboratory and in animals, and it is used to evaluate the safety and efficacy of a new drug or device. Pre-clinical research can help to identify potential problems with a new treatment, and it can help to determine the appropriate dose and route of administration.

Study Design

The design of a clinical trial is critical to its success. The study design should be based on the scientific objectives of the trial, and it should be tailored to the specific drug or device being studied. There are many different types of clinical trials, and the type of trial that is used will depend on the specific research question being asked.

Data Management

Data management is an important part of clinical development. The data that is collected during a clinical trial must be accurate and complete, and it must be managed in a way that protects the privacy of the participants. Data management is also essential for the statistical analysis of the data, which is used to determine the safety and efficacy of the new drug or device.

Statistical Analysis

Statistical analysis is used to interpret the data that is collected during a clinical trial. Statistical analysis can be used to determine the safety and efficacy of the new drug or device, and it can also be used to identify trends and patterns in the data. Statistical analysis is an essential part of clinical development, and it is used to make decisions about the future of the new treatment.

Regulatory Approval

Regulatory approval is the final step in the clinical development process. Regulatory approval is granted by a government agency, such as the Food and Drug Administration (FDA) in the United States. Regulatory approval is based on the results of the clinical trials, and it is used to determine whether the new drug or device is safe and effective.

Clinical development is a complex and expensive process, but it is essential for bringing new treatments to market and improving the lives of patients. This book provides a comprehensive overview of the clinical development process, from pre-clinical research to regulatory approval. It covers all aspects of clinical development, and it is packed with practical advice and insights.

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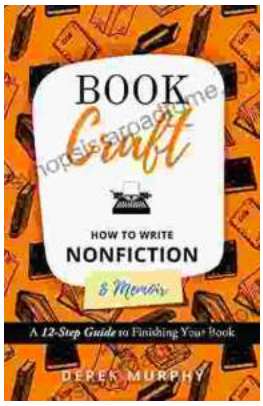

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