JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 9, No. 5, May 2013 "Happy Trials to You"

"New Drug Development: An Introduction to Clinical Trials, 2nd Edition"

J. Rick Turner, 2010, 256 pages, Springer, $189

Review by Norman M. Goldfarb

"New Drug Development: An Introduction to Clinical Trials, 2nd Edition" is a solid introduction to the process of drug development, with an emphasis on clinical research, especially the statistical aspects. It is ideal for readers interested in clinical research within the broader context.

This book has been selected for

The First Clinical Research Bookshelf

Essential reading for clinical research professionals

The book is written in a practical and straightforward manner, as shown by these examples:

Balancing the Degree of Flexibility Within an SOP

First and foremost, SOPs should be written in a clear, concise and unambiguous manner. Less clear is just how rigid they should be. This last statement may sound counterintuitive at first: should not these documents specify precisely what should happen in all eventualities? The pragmatic answer is no. A certain degree of rigidity is certainly necessary to ensure that processes operate smoothly, consistently and reliably within the company, and regulatory agencies will also expect to see this during an audit. However, SOPs should not be so onerous that their implementation impedes successful work proceeding at a reasonable rate, or so inflexible that, when the company cannot address certain eventualities within the scope of an SOP, they frequently become out of compliance.

The Term "Error" Does Not Imply a Mistake

It is important to note that the term "error" does not imply a mistake. It refers to the fact that, had a different random sample been taken from the same population, a different sample mean would have been obtained. Indeed, the words "error" and "random" are related in many instances in statistics. Error variance is variance due to random chance, as opposed to systematic variance that is the result of a systematic influence on the data. Randomization is a process whose purpose is to distribute error variance evenly across treatment groups so that it does not cloud our ability to detect any systematic variation that may be present.

The book includes 17 chapters:

- New Drug Development
- The Regulatory Environment
- Drug Discovery
- Nonclinical Research
- Designing Clinical Trials
- Conducting Clinical Trials I: Experimental Methodology
- Conducting Clinical Trials II: Operational Execution

- Statistical Analysis
- Statistical Significance
- Clinical Significance
- Sample Size Estimation
- General Safety Assessments
- Efficacy Assessment
- Cardiac and Cardiovascular Safety Assessments
- Manufacturing Small Molecule Drugs and Biologicals
- Postmarketing Surveillance
- Themes and Concluding Comments

The book is available in bookstores.

Reviewer

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