

"The Agile Approach to Adaptive Research: Optimizing Efficiency in Clinical Development"

Michael J. Rosenberg, 2010, 274 pages, John Wiley & Sons, \$79.95

Review by Norman M. Goldfarb

"The Agile Approach to Adaptive Research: Optimizing Efficiency in Clinical Development" presents adaptive methods of clinical research from three welcome perspectives. First, it discusses the use of adaptive methods in protocol design: dose-ranging, randomization, treatment switching, etc. Second, it expands adaptive concepts to study operations. Third, it explains how to obtain the real-time information needed to adapt with agility. Unlike other volumes that focus on the statistics of protocol design, this book includes almost no formulae and takes a much broader perspective. As a result, it is ideal for senior executives who want a strategic view of adaptive methods, managers looking for practical opportunities to significantly improve the efficiency of their operations, and statisticians interested in learning the broader ramifications of their arcane expertise.

This book has been selected for
[The First Clinical Research Bookshelf](#)
Essential reading for clinical research professionals

The core of the book is the practical application of adaptive methods to operations. There is certainly room for improvement. According to the author, a conventional study devotes 25-30% of its efforts to remediation, akin to the rework that has almost disappeared from modern manufacturing facilities. Adaptive operational methods can be implemented piecemeal, with immediate results. For example, the frequency of site monitoring visits can be adjusted to deliver maximum value at the sites that need help. However, a comprehensive approach will yield more substantial benefits. The author, the president and CEO of a contract research organization that has conducted hundreds of adaptive trials, "eats his own cooking," so presumably knows what works in practice.

The book consists of 10 chapters:

- Opportunity for Efficiency
- Defining and Extending the Adaptive Approach
- Design Adaptations Part One: Finding the Right Dose
- Design Adaptations Part Two: Additional Design Changes
- Operational Adaptations
- Agile Clinical Development
- Planning Adaptive Programs
- Statistics and Decision Making in Adaptive Research
- The Agile Platform
- The Future of Clinical Development

The book is available in bookstores.

Reviewer

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