

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

Michael J. Rosenberg



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Apply adaptive research to improve results in drug development

The pharmaceutical industry today faces a deepening crisis: inefficiency in its core business, the development of new drugs. *The Agile Approach to Adaptive Research* offers a solution. It outlines how adaptive research, using already-available tools and techniques, can enable the industry to streamline clinical trials and reach decision points faster and more efficiently.

With a wealth of real-world cases and examples, author Michael Rosenberg gives readers a practical overview of drug development, the problems inherent in current practices, and the advantages of adaptive research technology and methods. He explains the concepts, principles, and specific techniques of adaptive research, and demonstrates why it is an essential evolutionary step toward improving drug research and development.

Chapters explore such subjects as:

- The adaptive concept
- Design and operational adaptations
- Sample-size reestimation
- Agile clinical development
- Safety and dose finding
- Statistics in adaptive research, including frequentist and Bayesian approaches
- Data management technologies
- The future of clinical development

By combining centuries-old intellectual foundations, recent technological advances, and modern management techniques, adaptive research preserves the integrity and validity of clinical research but dramatically improves efficiency.

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