



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

By 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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Editorial Review

Review

"This book certainly brings the relevant issues upfront." (*Chemistry & Industry*, June 2010)

"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." (*Journal of Clinical Research Best Practices*, April 2010)

"Rosenberg captures the current excitement surrounding adaptive clinical research, and provides a very readable introduction to the methodologies involved in implementing such research." (*Journal for Clinical Studies*, March 2010)

About the Author

MICHAEL J. ROSENBERG, MD, MPH, is President and Chief Executive Officer of Health Decisions, Inc. Involved in the design and execution of pharmaceutical development programs for more than twenty-five years, Dr. Rosenberg was selected as Entrepreneur of the Year by Ernst & Young (Health Sector, SE). His company's innovative applications of technology have been recognized by the CIO Enterprise Value Award and the Cisco Growing with Technology Award. Health Decisions has also been named three times to the Deloitte & Touche Technology Fast 500 and the Inc. 500. Dr. Rosenberg is the author of more than 150 scientific articles and serves on advisory groups in business, technology, and medicine.

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Margaret Wynkoop:

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