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Autore	Rosenberg Michael J
Titolo	The agile approach to adaptive research [[electronic resource] ] : optimizing efficiency in clinical development / / Michael J. Rosenberg
Pubbl/distr/stampa	Hoboken, N.J., : Wiley, c2010
ISBN	1-282-54764-X 9786612547645 0-470-59968-5 0-470-59967-7
Descrizione fisica	1 online resource (296 p.)
Collana	Wiley series on technologies for the pharmaceutical industry
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Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	The Agile Approach to Adaptive Research: Optimizing Efficiency in Clinical Development; Contents; Preface; Acknowledgments; 1 Opportunity for Efficiency; The Adaptive Solution; An Industrial Success Story; Signs of Trouble Ahead; Converging Challenges; The Struggle to Replace Lost Revenues; Clinical Research Is the Key; Behind the High Costs of Clinical Development; High Costs and Increasing Prices; Growing Pressures Mandate Greater Efficiency; The High Risk of Current Development Practices; Economic Consequences of Faster Clinical Development; Thriving in a New Era; References 2 Defining and Extending the Adaptive ApproachThe Adaptive Concept; Knowledge, Time, and Decision Making; The Value of Early Knowledge; The Spectrum of Design and Operational Adaptations; Maximizing the Adaptive Approach: Agile Clinical Development; Measure Performance in Real Time; Metrics in Action; Right Information to the Right Eyes at the Right Time; Make Timely Decisions; Organize Work in Lean Processes; Rework in Clinical Studies; Backflow of Patient Data; Match Technology with Tasks; Objections to Adaptive Methods; Integrity and Validity; The Regulatory Environment The Complexity of Clinical ResearchConclusion; References; 3 Design

Adaptations Part One: Finding the Right Dose; Background; Types of Design Adaptations; Order of Discussion; Dosing Nomenclature; Determining Maximum Safe Dose; Single Arm; Continual Reassessment Method; Other Bayesian Dose-Finding Methods; Determining Optimal Dose (Pruning); Multiple Arms; Improvements over Conventional Approaches to Dose Finding; Dose Selection in Practice; Optimizing Dose Selection; Minimizing Costs Versus Maximizing Information; Surrogate Endpoints; Conclusion; References

4 Design Adaptations Part Two: Additional Design Changes Sample-Size Reestimation; The Trouble with Planning Estimates; The High Cost of "Underbuilt" Studies; The Benefits of Reestimation and Rightsizing; Reestimation and Trial Stages; Rules to Restrict Reestimation; Adjusting Sample Size for Nuisance Parameters; Seamless Designs: Combining Multiple Phases; When to Consider Seamless Studies; Seamless Phase I/Phase II Trials; Seamless Phase II/Phase III Trials; Planning Issues in Seamless Trials; Phase I-II-III Designs; Adaptive Randomization; Response-Adaptive Randomization

Other Forms of Adaptive Randomization Other Types of Design Adaptations; Noninferiority-to-Superiority Design; Adaptive Hypotheses and Subpopulations; Treatment Switching; Conclusions; References; 5 Operational Adaptations; Design and Operational Adaptations; The Nature and Significance of Operational Adaptations; Implementing Operational Adaptations; Enrollment and Other Site Issues; Data Quality; Monitoring; Site Closeout and Database Lock; Supporting Functions for Efficient Operations; The Bottom Line; References; 6 Agile Clinical Development; Benefits of Agile Development

A Development Example

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## Sommario/riassunto

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 in

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2. Record Nr.	UNISANNIOPAL0211604
Autore	Riga, Giulio
Titolo	Microsim : procedure automatiche di microzonazione sismica / Giulio Riga
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ISBN	9788877588043
Descrizione fisica	159 p. ; 25 cm. + 1 CD Rom
Collana	CD book Sistema microzonazione : collana per l'individuazione del rischio sismico locale e la valutazione delle conseguenze
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