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Nota di contenuto	Why Do Clinical Research?- How Clinical Research Should Never Have Been Done: Ethical Measures for Protection and Respect -- Choosing Studies -- Starting Clinical Research -- Developing a Budget -- Negotiating a Contract -- Writing a Great Informed Consent (IC) -- Starting the Study -- Regulatory Startup -- Recruiting -- Getting Subjects through the Door -- The Screening Visit -- Follow-up Visits -- Maintaining Subject Retention and Avoiding Study Fatigue -- Adverse Events (AE's) and Protocol Deviations -- Contact Research Organizations (CRO's) and Monitors -- Annual Review and Financial Disclosures -- Finishing a Study -- Staff Training and Incentives -- Study Closeout -- Acing an Audit -- Expanding the Team -- Epilogue: Watching Medicine Evolve -- Appendices.
Sommario/riassunto	This unique book is designed to help a medical team become a clinical research team. It includes practical information and tips for the initial stages of clinical research: building a team, negotiating a contract, developing a budget, and writing and improving a patient consent. Chapters describing the nuts and bolts of how to actually perform the study follow, including patient recruiting and retention, screening, follow-ups and handling monitor visits. Finally, there is discussion of the yearly reviews and disclosures and not just surviving, but acing, the all-important Food and Drug Administration audit. Clinical research moves medicine forward and is a necessary part of bringing any new therapy, device, or procedure into routine medical care. However, it can

be costly and convoluted, and the methodologies of clinical research are not widely standardized. Decreasing some of the chaos present in American clinical research is the primary goal of this book. The second goal is to improve the understanding and education of those who enter clinical research, whether in the frontline work of the clinical research site, in the middleman companies who have a high turnover rate, at a research hospital or institution, or at medical corporations that depend on good clinical research to bring their products to market. The third reason is to standardize American clinical research and to remove some of the vagaries and inconsistencies in the field. Practical and user-friendly, Developing a Successful Clinical Research Program fills a need for a clear guide to developing and improving a first-class research program in any clinical setting. .