



Physician Investigator Handbook: GCP Tools and Techniques, Second Edition (Practical Clinical Trials Series)

Deborah Rosenbaum, Fred Smith

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A comprehensive guide for physicians conducting clinical research, this second edition addresses a broader research perspective. It includes information on the implications of the ICH Guidelines, current FDA regulations, and an Internet address directory. Everything the clinical trial manager, planner, monitor, and investigator need to know about the design, establishment, monitoring, and close-out of a trial is in this book. The chapters address the elements of clinical research, professional interactions, FDA regulations and good clinical practices guidelines, investigational agent management, designing a study and protocol development, conducting the study, and more.



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