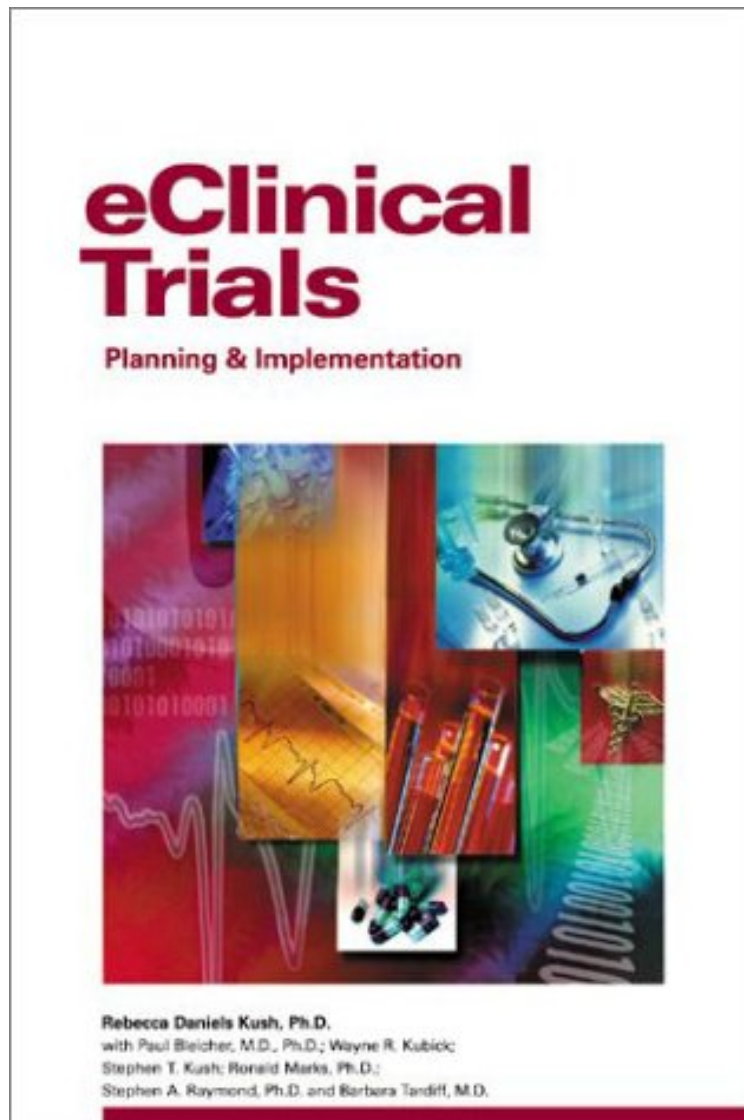


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## eClinical Trials: Planning and Implementation

*Rebecca Daniels Kush, Paul Bleicher, Wayne R. Kubick, Stephen T. Kush, Ronald Marks, Stephen A. Raymond, Barbara Tardiff*

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methodically moves through the process of applying electronic data capture and other electronic technologies to existing workflows. It paints a realistic picture, giving credence to the advantages of using EDC and CTMS while including frequent reality checks, acknowledging the relative infancy of these technologies. I used this book as a part of my study curriculum for preparing for the Certified Clinical Data Manager (CCDM) examination, and I believe it helped immensely. I especially recommend the book if you're preparing for that exam. 0 of 0 people found the following review helpful. Five Stars By Customer Great product and price 6 of 6 people found the following review helpful. An excellent guide! By Rlafleur "eClinical Trials: Planning Implementation" is an excellent guide for clinical researchers interested in taking advantage of the electronic technology that is becoming increasingly available. In such a highly-regulated industry, there are a lot of questions before someone moves from the comfortable environment of paper-based clinical trials to the less-familiar ground of electronic records. This book addresses such topics as data quality and data integrity, safety surveillance and IRBs, and the regulatory environment's intent and impact on clinical trials. The material in this book is presented in a way that can help a researcher understand the implications using the new technologies and processes in planning and implementing a clinical trial.

eClinical Trials: Planning and Implementation This new manual - the first-of-its-kind - is an invaluable resource designed to assist biopharmaceutical companies, CROs and investigative sites in understanding, planning and implementing electronic clinical trial (eCT) technology solutions to accelerate and improve their research operations. Written by highly respected and authoritative thought leaders in the field today, this 200+ page book describes and addresses the concepts and complexities of managing and conducting an optimal eCT, while offering practical guidance, facts and advice on implementing eCT technologies. eClinical Trials: Planning and Implementation will be routinely referenced by scientific, administrative and clinical IS personnel when planning and implementing eCT technology strategies. Book features... \* Understanding how eCT technology solutions can accelerate and improve clinical research processes \* Identifying ways to redesign the research processes in order to optimize the advantages of various eCT technologies \* Considerations for establishing quantitative metrics to measure and track the impact of eCT technology implementation \* Understanding and applying the intent of 21CFR11 and data privacy requirements and the value of data interchange standards \* Comprehending the value of data interchange standards and how to ensure high quality data for clinical trials Perfect for: \* Investigators, study nurses, pharmacists and other research professionals \* Instructors conducting training and educational programs \* Sponsors, CROs, SMOs and academic institutions conducting clinical trials

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