



Guide for Investigator Initiated Trials

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For academic medical faculty unfamiliar with national and international regulations, the prospect of initiating and managing a clinical trial can be intimidating. The development of protocols and case report forms, compliance with regulatory requirements, the monitoring of clinical trials as well as the responsibilities of documentation are just some of the tasks the sponsor-investigator is faced with. This book covers the entire spectrum of a clinical trial, reviewing the different stages step by step: financial planning, crucial aspects of trial design, the authorization process and, finally, documentation. Moreover, it contains helpful tips, a practical glossary, instructions and a large number of resources related to the relevant regulations and forms conforming to the 'International Conference on Harmonization and Good Clinical Practice'. This makes the publication at hand an essential 'cookbook' for both academic faculty new to clinical trials as well as seasoned sponsors-investigators.

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