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The first journal to focus on the fetus as a patient, 'Fetal Diagnosis and Therapy' provides a wide range of biomedical specialists with a single source of reports encompassing the common discipline of fetal medicine. The journal comprehends sections such as Mini Reviews, where specific questions of clinical interest are addressed by internationally renowned experts in the field, or Images in Fetal Medicine, which aims at exploiting the huge amount of images that the practice of fetal medicine generates, with particular interest in documenting cases with multimodal imaging. 'Fetal Diagnosis and Therapy' offers a selection of peer-reviewed original research papers ranging in scope from basic and pathophysiologic investigations to clinical studies in fetal diagnosis and therapy.

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Guide for Investigator Initiated Trials

Editor
Gerhard Fortwengel

In collaboration with:
Isabel Böckler, Rafael Dymek, Sebastian Häckl, Alexander Hahn, Katrin Hertwig, Cynthia Kuhn, Birgit Lindner, Sarah Lütkens, Christoph Neumann, Marcus Paul, Madlen Pomp, Nadja Schachteli

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' and the European legislation. 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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