

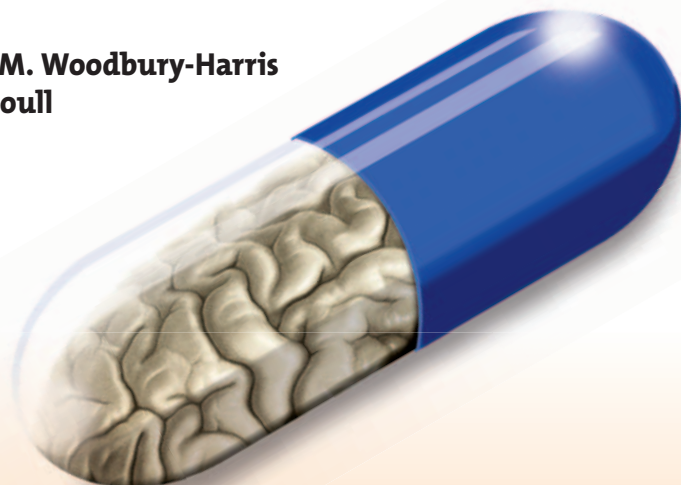
A comprehensive and practical overview

# Clinical Trials in the Neurosciences

Editors

**Katherine M. Woodbury-Harris**

**Bruce M. Coull**



A properly designed and executed clinical trial that addresses an important question and delivers a definitive result can change the practice of medicine worldwide. This book encompasses a bench-to-bedside approach and serves as an excellent guidance for translating preclinical studies to early phase I/II and phase III trials. In the first part, the book covers preclinical science with respect to animal models of various neurological diseases, FDA requirements for preclinical studies, translation of animal to patient studies and scaling up from animal to human studies. In the second part, the design of phase I/II trials and the use of biomarkers as surrogate endpoints are discussed. With regard to phase III trials, FDA and European requirements, specific design issues, relevant clinical endpoints as well as data management and quality are examined. Topics specific to multicenter trials, such as design, recruitment of special populations, monitoring, ethical and consent issues are also covered. Finally, genetics, gene therapy, imaging and surgical devices are reviewed.

This publication is highly recommended to clinician researchers, such as neurologists, neurosurgeons, pediatric neurologists and neonatologists, who want to design and conduct clinical trials in the neuroscience, but also to nurses, research coordinators and clinical pharmacologists.

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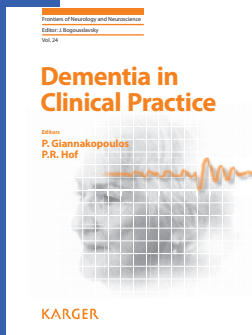
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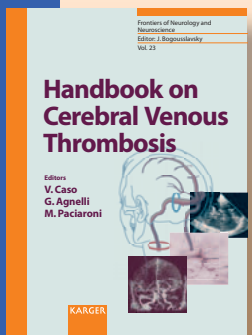
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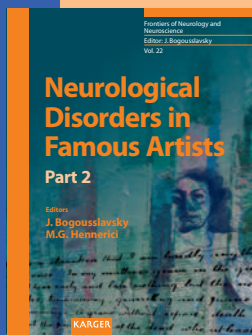
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