



# Clinical Trials, Second Edition: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines

By Tom Brody PhD

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*Clinical Trials, Second Edition*, offers those engaged in clinical trial design a valuable and practical guide. This book takes an integrated approach to incorporate biomedical science, laboratory data of human study, endpoint specification, legal and regulatory aspects and much more with the fundamentals of clinical trial design. It provides an overview of the design options along with the specific details of trial design and offers guidance on how to make appropriate choices. Full of numerous examples and now containing actual decisions from FDA reviewers to better inform trial design, the 2nd edition of *Clinical Trials* is a must-have resource for early and mid-career researchers and clinicians who design and conduct clinical trials.

- Contains new and fully revised material on key topics such as biostatistics, biomarkers, orphan drugs, biosimilars, drug regulations in Europe, drug safety, regulatory approval and more
- Extensively covers the "study schema" and related features of study design
- Incorporates laboratory data from studies on human patients to provide a concrete tool for understanding the concepts in the design and conduct of clinical trials
- Includes decisions made by FDA reviewers when granting approval of a drug as real world learning examples for readers

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### **Editorial Review**

#### **About the Author**

Dr. Tom Brody received his PhD from the University of California at Berkeley in 1980, and conducted postdoctoral research at University of Wisconsin-Madison and also at U.C. Berkeley. His 20 research publications concern the metabolism and pharmacology of folates, cloning an anti-cancer gene (XPE gene), and the structure of an antibody (natalizumab) used for treating multiple sclerosis. The author has 15 years of pharmaceutical industry experience, acquired at Schering-Plough, Cerus Corporation, and Elan Pharmaceuticals, and has contributed to FDA submissions for the indications of multiple sclerosis, melanoma, head and neck cancer, liver cancer, pancreatic cancer, and hepatitis C. At an earlier time, he wrote two editions of Nutritional Biochemistry, published by Elsevier, Inc. The author has 16 years of training and experience in the Code of Federal regulations, as it applies to pharmaceuticals and clinical trial design.

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