DESCRIPTION

Best practices for conducting effective and safe clinical trials

Clinical trials are arguably the most important steps in proving drug effectiveness and safety for public use. They require intensive planning and organization and involve a wide range of disciplines: data management, biostatistics, pharmacology, toxicology, modeling and simulation, regulatory monitoring, ethics, and particular issues for given disease areas. Clinical Trials Handbook provides a comprehensive and thorough reference on the basics and practices of clinical trials.

With contributions from a range of international authors, the book takes the reader through each trial phase, technique, and issue. Chapters cover every key aspect of preparing and conducting clinical trials, including:

• Interdisciplinary topics that have to be coordinated for a successful clinical trial
• Data management (and adverse event reporting systems)
• Biostatistics, pharmacology, and toxicology
• Modeling and simulation
• Regulatory monitoring and ethics
• Particular issues for given disease areas—cardiology, oncology, cognitive, dementia, dermatology, neuroscience, and more
With unique information on such current issues as adverse event reporting (AER) systems, adaptive trial designs, and crossover trial designs, *Clinical Trials Handbook* will be a ready reference for pharmaceutical scientists, statisticians, researchers, and the many other professionals involved in drug development.

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**ABOUT THE AUTHOR**

Shayne Cox Gad, PhD, DABT, ATS, is the Principal of Gad Consulting Services. Dr. Gad has more than thirty years of experience as a toxicologist, statistical consultant, manager, and general consultant on research and development in the chemical, consumer product, contract testing, biotechnology, medical device, and pharmaceutical industries. He is the author of thirty-nine books and numerous papers, presentations, and other publications.

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