



Phase I Cancer Clinical Trials: A Practical Guide

Elizabeth A. Eisenhauer, Christopher Twelves, Marc Buyse

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Phase I trials are a critical first step in the study of novel therapeutic approaches. They follow years of development in the laboratory, and precede Phase II and III trials where testing of the drug becomes more focused yet is conducted on a wider scale. The primary goals of Phase I trials are to identify the recommended dose, schedule and pharmacologic behaviour of new agents or new combinations of agents, and to describe the adverse effects of treatment. In cancer therapeutics, such studies have particular challenges. In general, because of the nature of the effects of treatment, most studies are conducted in patients with advanced malignancy, rather than in healthy volunteers. Furthermore, the endpoints of these trials are usually measures of adverse effects, but increasingly investigators are interested in assessment of the effects of new drugs on their molecular target. These factors render the design, conduct, analysis and ethical aspects of Phase I cancer clinical trials unique. This book provides a practical guide to Phase I cancer trials and is appropriate for oncology trainees or specialists interested in understanding cancer drug development. Topics covered include preclinical requirements needed for first-in-man investigation of new agents, principles and statistical design, ethical considerations of Phase I studies, pharmacokinetics, pharmacodynamics, and studies in special populations. Practical information on protocol development, study activation and conduct, as well as how to write reports of the results, are incorporated. Numerous appendices offer document templates to use in Phase I study development, and examples from actual Phase I trials are interspersed throughout, making this a true 'hands-on' guide. In an exciting time in cancer research, as the number and type of new potential anti-cancer drugs is increasing dramatically, this book provides much needed information on the first stage in get

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