



Phase I Cancer Clinical Trials: A Practical Guide

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Phase I trials are a critical first step in the study of novel cancer therapeutic approaches. Their primary goals are to identify the recommended dose, schedule and pharmacologic behavior of new agents or new combinations of agents and to describe the adverse effects of treatment. In cancer therapeutics, such studies have particular challenges. Due to the nature of the effects of treatment, most such studies are conducted in patients with advanced malignancy, rather than in healthy volunteers. Further, the endpoints of these trials are usually measures adverse effects rather than molecular target or anti-tumor effects. These factors render the design, conduct, analysis and ethical aspects of phase I cancer trials unique. As the only comprehensive book on this topic, Phase I Cancer Clinical Trials is a useful resource for oncology trainees or specialists interested in understanding cancer drug development. New to this edition are chapters on Phase 0 Trials and Immunotherapeutics, and updated information on the process, pitfalls, and logistics of Phase I Trials

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