

# Design of Phase I and II Clinical Trials in Oncology and Ethical Issues Involved

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## Abstract

**Introduction:** There are 2 broad classes of anticancer drugs that require different approaches to development. The classical cytotoxic agents have low therapeutic indices and therefore traditionally have different developmental strategies from non-oncology agents. The newer anticancer agents that target the signal transduction pathway and antiangiogenesis pathway have characteristics similar to non-oncology agents and will change the paradigm for drug development in oncology. **Methods:** To review the issues involved in phase I and II cancer trials, and to describe how these issues have been addressed. **Results and Conclusions:** There are significant scientific and ethical issues in phase I and II cancer clinical trials, which influence the design of these studies. Nonetheless, these trials are vital for the successful development of anticancer agents. The development of novel anticancer agents that target signal transduction and antiangiogenesis has posed great challenges, and changes in the conventional cytotoxic paradigm of development are expected for these agents.

*Ann Acad Med Singapore 2000; 29:588-97*

**Key words:** Cytotoxics Development, Drug, Ethics

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