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Introduction

Recent progress in biotechnology research is causing a dramatic broadening of therapeutic tools in oncology. The first monoclonal antibodies have already been registered and numerous additional biological approaches are emerging. Not only have vaccines been broadly introduced into clinical trials, but inhibitors of angiogenesis or signal transduction as well as gene therapy are also moving towards phase III trials. Many upcom-

ing drugs will cause a shift from disease oriented to target-oriented cancer therapy and be cytostatic rather than cytotoxic. Therefore, new strategies for early clinical trial design are required and pose a fascinating challenge for both academia and industry. Biotech research is an extremely competitive field and rational drug development is not only required for scientific and ethical reasons but will also reduce developmental costs of new drugs.