

ADAPTIVE DESIGN ALTERNATIVES



How to Maximize the Effectiveness of Phase I and Phase II Oncology Studies

ADAPTIVE TRIAL DESIGNS ARE A HOT TOPIC IN ONCOLOGY DRUG DEVELOPMENT, ESPECIALLY IN PHASE I AND PHASE II STUDIES

An adaptive trial provides the greatest impact when you don't have enough data to design a traditional trial with confidence — which is common in early stage studies.

OUR OFFERING

Medelis can analyze your drug and create a design outline for an adaptive trial for your phase I or phase II study. This short-term consulting engagement can have a dramatic impact on your clinical development path — delivering faster data to reduce your time to market.

VALUE

Adaptive trial designs in phase I and phase II oncology studies can result in:

- A greater chance of phase III success by obtaining superior information in phase I and phase II
- Fewer patients receiving ineffective doses
- An opportunity to combine proof of concept with dose escalation in particular cases
- Fewer patients required in phase II and in phase III
- Faster study outcomes
- Reduced time to market; reduced spending during development



ABOUT MEDELIS:

As a single-source provider for clinical trial planning, trial management, and drug development planning, Medelis delivers the best total solution—and all the support required—for biotechnology and pharmaceutical companies to optimize their return on clinical research investments. And we accomplish that in the quickest, most responsive way possible.

OUR EXPERIENCE:

Medelis' medical founders, team physicians and advisors are internationally-recognized oncology thought leaders. They organize and chair sessions at national and international oncology meetings and serve as officers and board members of professional oncology organizations, including The American Association for Cancer Research and The American Society of Clinical Oncology.

Our clinical operations team and medical personnel have critical first-hand experience with the complex issues often associated with oncology clinical trials, and they have handled most targets in oncology, which means that highly experienced resources will be working on your study.

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