Worldwide Clinical Trials

Adaptive Trial Design — Is It Right For Your Clinical Study?

Adaptive clinical trials differ from typical trials in their inclusion of pre-planned adaptations to the trial design without the requisite need for a formal protocol amendment. By utilizing the data accumulated throughout the study, alterations can be made to the original methodology, such as a change in the dosage evaluated, the patient population, the study duration based on futility or overwhelming efficacy, or the sample size based on contemporary regulatory guidance.

Here are some things to consider when developing a strategy for your study:

What are your development goals?

If your study requires quick timelines with less time between clinical phases, includes defining specific sub-groups of patients, and/or leverages de-risking strategies, then an adaptive trial design may be an effective strategy to reach your development goals.

Would allocating treatment groups mid-trial based on phenotypic or genotypic information be productive?

A biomarker-guided adaptive design in oncology, for example, focuses specifically on identifying cancer biomarkers. Patient cohorts may then be added or removed in accordance with their response to therapy following an interim analysis of data.

Learn more about the essential role biomarkers play in oncology development →

Do you have the best team in place?

It's important to ensure clinicians, trialists, and statisticians have sufficient experience and expertise to manage the additional operational planning and biostatistical analysis. Adaptive designs can be difficult to execute and require careful design and operational implementation by experienced teams, like our Clinical Research Methodology team.

Is adaptive design always the best choice for your indication and trial?

Adaptive designs are increasingly being used successfully across a wide range of therapeutic indications, with frequent use in oncology and rare disease studies. Additionally, there is substantial past precedent and industry support for these trials taking place in other disease settings.

Benefits Include:

- Potential for lower costs and study efficiencies
- Optimized development program
- Regulatory guidance that enables design, operations, and analyses
- More patients exposed to optimal dose and regimen
- Multi-stakeholder appeal, including patients and physicians

Worldwide Clinical Trials' extensive adaptive trial knowledge, from protocol design through data collection and analysis, can help you fully realize the potential benefits of adaptive trial design methodology. Discuss your trial with Worldwide's Clinical Research Methodology team to see if an adaptive approach could support the advancement of your program.

Let's talk →