# Clinical Trials Meet Adaptive Design

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## Side-by-Side Comparison: Non-Adaptive vs. Adaptive Designs in Clinical Trials

Adaptive design clinical trials are accelerating the movement of new therapies from concept to market with the ethical advantage of reducing patient exposure to ineffective or unsafe experimental treatments.

| Key Feature | Non-Adaptive Clinical Trials | Adaptive Clinical Trials |
|---|---|---|
| **Definition** | Clinical trials planned and executed according to a study protocol that does not include modifications. | Clinical trials with prospectively planned modifications to one or more aspects based on accumulating trial data.[1] |
| **Interim Data Analysis** | Interim analysis can occur with no planned study modifications. | Pre-specified interim analysis for review with planned modifications based on accumulating data, including early stopping of ineffective treatments for futility. |
| **Type I Error Control** | Standard methods to control for testing of endpoint(s). | Requires advanced statistical methods, such as alpha-spending functions, to maintain validity with interim looks; appropriate methods depend on the planned adaptations. |
| **Sample Size** | Fixed sample size, specified ahead of trial initiation in the study protocol. | Pre-specified sample size re-estimation at an interim timepoint can be included. |
| **Statistical Power** | Fixed power calculations specified ahead of trial initiation in the study protocol. | Pre-specified sample size re-estimation or population enrichment can increase statistical power. |
| **Added Operational Complexity*** | Low with a fixed study design. | Can be high, particularly when modifications result from unblinded interim analyses. |
| **Added Risk of Operational Bias*** | Low with a fixed study design. | Can be high due to changes in behavior of study staff, patients, or enrolled population. Must guard against bias using rigorous processes and oversight. |
| **Regulatory Oversight** | Follows established pathways, may require fewer real-time interactions with agencies. | Requires proactive, ongoing engagement with regulatory authorities to justify the planned design, statistical analysis methods, and bias mitigation strategies. |
| **Development Program Efficiency** | May have higher spend and longer timelines to approval, as unproductive studies continue until completion. | May reduce costs and accelerate timelines by enabling early stopping, dose selection, sample size re-estimation, or population enrichment. |

*Implementation of an adaptive design can add to the already present study operational complexity and risks of operational bias.

Adaptive designs require more upfront planning but may offer significant long-term advantages, including accelerated timelines, lower costs, and stronger evidence for decision-making.

**Learn more about how Veristat can support your adaptive design trial:**
**veristat.com/adaptive-designs ›**