



4 Ways to Know Adaptive Trial Design Is Right for Your Trial

Adaptive trial design is a wide umbrella term for any design that changes during a trial, but in a prespecified manner. This allows for planned modifications to one or more aspects of the design, shifts based on accumulating data that allow for earlier go/no-go decisions and the ability to potentially answer more questions than traditional drug development.

Here is when to consider adaptive trial design:

- 1. Is there dose selection uncertainty?** For example, in early phase oncology, model-based adaptive designs can mean fewer patients may be assigned to a less promising dose, or recruitment to futile treatment arms may stop early.
- 2. Is your estimate of variability as reliable as it could be?** If you have only performed a small Phase II and have uncertainty about your estimate but need to move forward in development, sample size re-estimation can help you pivot and ensure you are providing the best probability of success.
- 3. Are you looking at subgroups in tumor types and want to be able to shift based on accumulating data?** Being able to enrich your patient population or subgroup means you will position your trial better with regulatory agencies if you are adapting in a prespecified manner.
- 4. Is your trial for rare/orphan diseases?** Since there is not a large patient pool, using adaptive trial design can mean that decisions can be made quickly and patient data can be used not just in your trial but any trial that's in that indication, ensuring you are not taking any patient from other research that could also be feasible.

Benefits to adaptive trial design include the ability to allocate resources internally and increase the chances of getting to market faster. Adaptive trial design may also increase chances of success with smaller expected sample size, as well. Adaptive trial design may not be right for every trial, but when it is appropriate, it can help provide a higher chance of success.

Considering adaptive trial design? [Contact us](#) to find out how it can increase the success of your trials.

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