

Adaptive Clinical Trials: Meaning, Benefits and Challenges

Developing a brand new pharmaceutical product is lengthy and costly process. For the past several decades it has been indicated that **the extensive research does not equal extensive and productive results** which turns out to be a real drawback. The lack of sufficient development in the form of new medicines has challenged a number of regulators and researchers to look for advanced methods that will help reduce the unacceptably low level of productiveness. Finding out that **the classically structured design of clinical trial does not offer complete satisfactory standards**, specialists in the Pharmaceutical sector seek innovative trial designs. One such design is the adaptive design in clinical trials suggested by the Food and Drug Administration (FDA).



What is adaptive design clinical trial?

In every industry success has its price. When we talk about the Pharmaceutical sector though, that **price sometimes comes at major expenses and substantial amount of time dedicated to one project that may turn out to be inefficient at the end**. Having realized that the quickly escalating costs and complexity of work often may result in failure urges professionals to search for alternatives. Recommended by the FDA, **the adaptive design clinical trials represents a revolutionary approach that bridges the gaps between initial research and successful new drug development**. Unlike the classic designs of clinical studies, this one provides with the flexibility needed in the Pharma world to regulate trials as much as possible. To present this differently, the adaptive design **gives an opportunity to researchers to monitor and evaluate patients' reactions** to a drug at an early stage in a clinical trial. This enables them to modify and adapt the direction of the trial according to what has been indicated and found before that. Some alterations may include sample size, dosage and even duration of the drug trial. Of course, **such adaptations and modifications cannot be done at any time**. Instead they have to be pre-defined, carefully planned in advance and, as mentioned before, based on the information gathered from the on-going study.

What is the aim of the adaptive design clinical trial?

There are **several purposes for the implementation of the adaptive design**, including: distinguishing more quickly the medical product that has a therapeutic effect on patients; making clinical trials more effective, flexible and less long-lasting.

Types of adaptive designs

The most commonly used adaptive designs in clinical trials are:

Adaptive randomization design: **adaptive randomization design methods allow for changes in the allocation of subjects**, depending on the information collected from the treatment. Such procedures **lead to boosted statistical power, reduced selection bias and minimized allocation bias**. There are two types of adaptive randomization designs - **covariate and response** adaptive randomization.

Biomarker-adaptive design (also known as enrichment target clinical trial design): it is used to make sure that candidates for a specific clinical trial are likely to demonstrate effects from the given treatment. In other words, the biomarker-adaptive design **serves to identify people as either good or poor volunteers that can help for the optimization of the treatment selection**.

Group sequential design: with the implementation of this design a trial can be stopped before its completion in case there **are issues in terms of safety and efficacy**. Additional alterations can be made based on the interim examination.

Other types of adaptive designs in clinical researches are: a two-stage phase I/II (or phase II/III) seamless adaptive trial design; flexible sample size re-estimation design (also called an N-adjustable design), a drop-the-loser design (known as a pick-the-winner design), an adaptive treatment-switching design, a hypothesis-adaptive design, a multiple adaptive design and an adaptive dose finding (escalation) design.



What are the benefits and challenges of adaptive design clinical trials?

The use of adaptive design methods in clinical research and drug development carries certain advantages. For instance, **if there are incorrect conclusions made at the beginning of the trial, the adaptive design will enable the investigator to fix them**. Another positive use of such design results in the availability to choose the most workable option at an early stage. What is more, adaptive

designs are **likely to cut the development time and, respectively, accelerate the overall development process.**



Yet, regardless the flexibility and the abundance of operative characteristics contained in the adaptive design there are **some concerns which possible to arise.** Such concerns are **closely linked to the quality, integrity and the moral values of clinical studies.** In this regard, among the most challenging aspects which those designs should tackle are the difficulties of interpreting results of the trial when the treatment effect has already

been revealed. Thus, because of the adaptations and modifications carried out throughout the course of the research, **analyzing the study outcomes becomes more complex.** Another challenge is for the investigator to **remain objective while managing individual patients.** Because some adaptations require unblinding of analysts that answer for the implementation of the pre-determined design revisions, the direct access to such analysts might affect negatively the assessment conducted by the personnel.

In conclusion, **adaptive designs have received major attention in the pharmaceutical and medical field.** The correct adoption of such designs in clinical researches **addresses a few particularities in a trial such as integrity, quality and validity.** Thanks to the flexibility of the adaptive design the ways in which pharmaceutical products are discovered, generated and brought into the market have been improved immensely.

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