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Key Methodologies and Principles of Adaptive Designs for Clinical Trials

Author : Mukesh Kumar

Due to the key amendments that have been applied to clinical trials over the recent years by both pharmaceutical and biotech companies, the significance of adaptive designs to clinical trials has become more obvious to the industry. The reductions in time and cost in the early stages of clinical trials allows fewer recruitment of patients and perks up the general accuracy in clinics. However, successful execution of adaptive designs into a trial needs unmatched coordination between trial managers, clinicians, statisticians and all those concerned with the regulation process. Listed are a few methodologies and principles of Adaptive Designs for clinical trials.

1. Indications Considered Using Adaptive Clinical Trials

Quick response to drug expected (pain, cholesterol-lowering), Orphan indications and Life-threatening indications (cancer, stroke).

2. Need for Adaptive Design

Adaptive Design is required for more efficient information analysis. Adaptive design increases likelihood of success on study objective, it yields improved understanding of treatment effect.

3. Benefits of Adaptive Design

The main benefits of adaptive design are: Early characterization of safety and efficacy, more data on dose of interest, better characterization of dose response, reduced risk of late failure (early rejection of inappropriate dose, regimen, indication, etc), better recruitment: higher subject acceptance and faster, cheaper trials.

4. Major risks of Adaptive Design

Some of the major risks of Adaptive Designs are: Regulatory acceptance of trial design, case-by-case approval, checks of data integrity, confidentiality and bias, statistical planning, justification of sample size for interim analysis, adjustment of study parameters such as randomization, endpoint analysis (non-inferior, superior).

5. FDA Guidance Document released in Feb 2010

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FDA Guidance Document released in Feb 2010deals with aspects of adaptive design trials (i.e., clinical, statistical, regulatory) that call for special consideration, when to interact with FDA (i.e. while planning and conducting), what to include for FDA review and issues to consider in evaluating completed adaptive design study.

6. Adaptive Design and statistical analyses

Adaptive design affects multiple aspects of statistical analyses like inflated Type I error rate, the bias point estimates, larger/smaller Confidence Intervals, hard to assess the impact.

7. Inflated Type I error rate

Inflated Type I error rate has a major impact as it can move a trial from a successful trial to a failed trial or other way around. The 0.05 two sided test may not be valid anymore. The statistical power may not be the 80% that we started with any more Addressed.

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