5 Things You Need to Know About Bayesian Response-Adaptive Design

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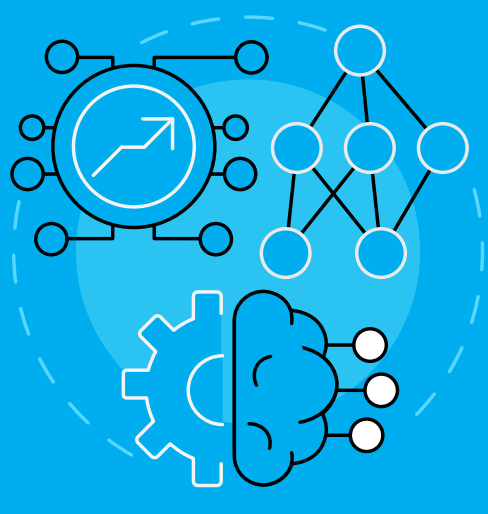
1 Dose-Finding

Bayesian response-adaptive design is a common approach used in phase 2 studies where the goal is to identify the optimal dose(s) for phase 3 studies to confirm efficacy.



2 Benefits

Prior assumptions can be adjusted based on accumulating data according to pre-defined adaptations and ineffective doses can be dropped as the study progresses.

3 Study Design

Bayesian response-adaptive design studies involve two stages:

Stage 1: Fixed randomization *(burn-in)*

Stage 2: Responsive-adaptive randomization

Enroll patients with equal randomization to all doses* and placebo

**Bayesian response-adaptive design is the most efficent with at least 5 dose levels.*

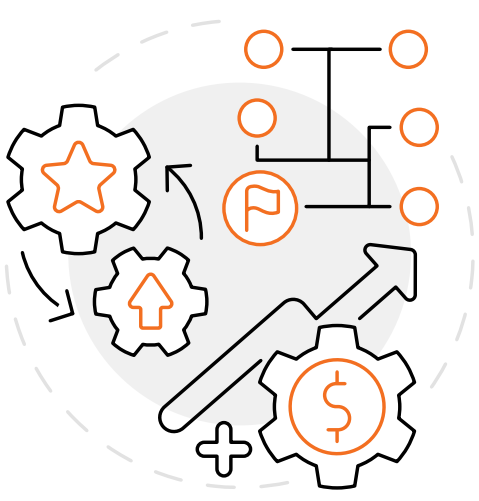
Analyze available data and generate updated success probabilities for each dose

Drop dose(s) with updated probability less than the pre-specified threshold

Use updated probabilities to define new treatment allocation rules

Accrue new patients based on new allocation rules

4 Operational Factors



- Requires multiple interim analyses while maintaining the blind
- Involves increased effort for site monitoring and data management
- Requires Data Safety Monitoring Board

5 Statistical Complexity

FDA requires extensive statistical simulations to understand the operating characteristics of the trial under many different assumptions, which may add time to the study.

Want to Learn More About Other Alternative Trial Designs?

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