East

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ADAPTIVE SAMPLE SIZE RE-ESTIMATION IN EAST®

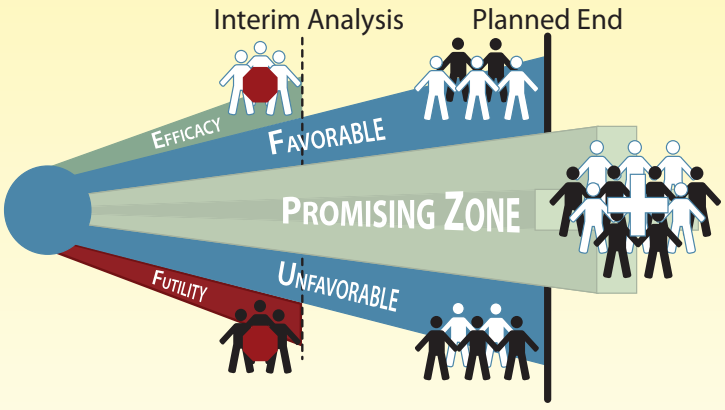
REDUCE RISK AND ENHANCE YOUR CLINICAL TRIAL SUCCESS

- **DE-RISK INVESTMENT – Avoid expensive up-front commitments of sample size**
- **ENHANCE SUCCESS – Boost power when initial assumptions fail**
- **PROMISING ZONE™ – Increase sample size conditional on interim data**
- **ALPHA CONTROL – Guarantee strong type I error control required by regulators**

PROBLEM

With half of all pivotal trials ending in failure, sponsors face considerable losses when committing to up-front investments especially for late stage, pivotal studies. Large sample sizes are necessary to ensure sufficient power, but uncertainty about treatment effects makes each study an expensive gamble.

Adaptive approaches can mitigate such risks, but how can you ensure the study's integrity and statistical validity are maintained?



SOLUTION

Designing trials in East effectively de-risks your trial by adaptively increasing the sample size and boosting power should initial assumptions fail. East users quickly construct a variety of design scenarios, run simulations to assess parameter tradeoffs and determine the optimal point for interim analysis.

Of prime importance, East ensures preservation of type-1 error control to fully comply with the FDA and EMA guidance for adaptive trials.

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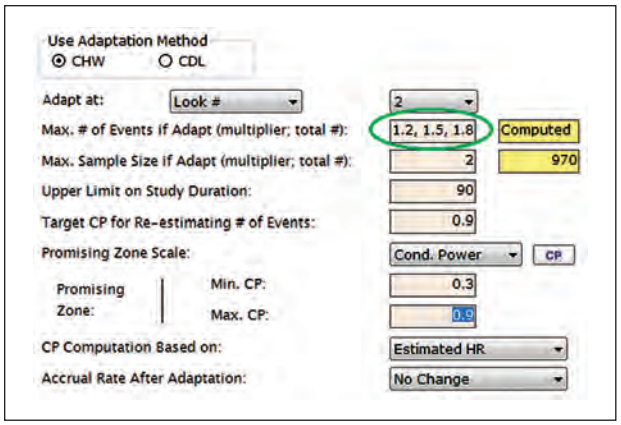


Adapt based on look number, interim sample size, or information scale

Define the Promising Zone™ based on conditional power, test statistic, or estimated effect size

Try out multiple adaptation rules to select the optimal one for your trial

Vary accrual and dropout patterns to perform sensitivity analysis

Enter multiple values of all these parameters to fine-tune the design

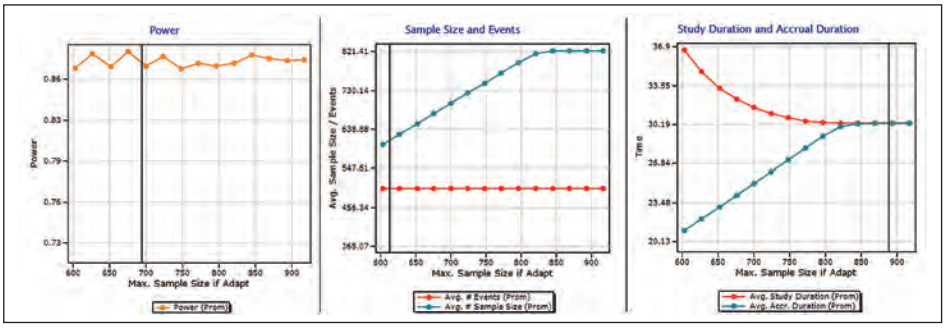
METHODS – Adaptation based on published methods by Mehta and Pocock (2011); Cui, Hung, and Wang (1999); and Chen, DeMets, and Lan (2004)

ENDPOINTS – Designs for Normal, Binomial, Survival endpoints

TOOLS – Simulations, Interim Monitoring, Conditional Power calculator

Compare designs on power, sample size and number of events, study duration and accrual duration

Evaluate the trade-off between accrual duration, sample size, and study duration to optimize your clinical trial design



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Cui L, Hung HM, Wang SJ. Modification of sample size in group sequential clinical trials. Biometrics. 1999 Sep; 55(3), 853-7.

Chen YH, DeMets DL, Lan KK. Increasing the sample size when the unblinded interim result is promising. Statistics in Medicine. 2004 Apr; 23(7), 1023-38.

FDA. Guidance for industry: adaptive design clinical trials for drugs and biologics. 2010.

Mehta CR, and Pocock SJ. Adaptive increase in sample size when interim results are promising: a practical guide with examples. Statistics in Medicine. 2011 Dec; 30(28), 3276-84.

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