Ethical Issues in Adaptive Clinical Trials (Session 2)

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Adaptive Decision Rule

- **power**
  The probability of success (statistical significance) at the end of the trial given current data trend

Interim outcome partitioned into unfavorable, promising, and favorable zones
Ethical issues

- What did they know, and when did they know it?
  - Are investigators informed of the design?
  - Are patients informed of the design?
Ethical issues

- If the sample size is not increased...
  - The results may be either favorable or unfavorable

- If favorable
  - Why not adopt adaptive randomization?

- If unfavorable
  - Could investigators figure this out (e.g., external information ➔ unblinding)?
  - Could this cause enrollment bias?
  - Should the subjects be informed? Why not?