

KIOSC

Korean Incubating Organization for Small Church


Adaptive Trial Design

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Last week

- **Observational/Experimental Study**
- **Trial Designs (Parallel, Cross-over, Factorial, Sequential)**
- **Power and sample size**

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Adaptive Design - Definition

“clinical trial design that allows for **prospectively planned modifications** to one or more aspects of the design **based on accumulating data** from subjects in the trial”

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Adaptive Design - Definition



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Ways to adapt

- Allocation
- Sampling
- Stopping
- Decision

=> Basically, almost all parts of the trial

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Used for

- Dose finding study
- Phase II/III seamless study
- Basket trial
- Umbrella trial

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Cautions

- Doesn't necessarily guarantee efficiency
- Flexibility at the cost of Complexity
- Challenges in interpretability of results

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Interim analysis for adaptation

- Non-comparative data (blinded analysis)
- Comparative data (unblinded analysis)

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Scenarios

- Group sequential designs
- Sample size re-estimation
- Patient population
- Treatment arm selection
- Patient allocation
- Endpoint selection

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Other considerations

- Simulation
- Bayesian adaptive
- Potential surrogate or intermediate endpoint
- Adaptation based on a source outside of trial

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Here we go....

Once agreement has been reached on the objective, it is the statistician's responsibility to provide the appropriate design and statistical inferential structure required to achieve that goal



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Thank You

Biostatistics for Non-statistician

- ☐ Basic I - Various Statistical Analysis Methods I
- ☐ Basic II - Various Statistical Analysis Methods II
- ☐ Advanced I - Study Design and Power & Sample Size
- ☐ Advanced II - Adaptive Trial Design

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