Bayesian Statistics

FDA Recommendations

Brani Vidakovic

Professor

School of Industrial and Systems Engineering

Arguments of FDA

Before We Begin...

FDA 2010 Guidelines (for medical devices)

- Valuable prior information is often available for medical devices
    - As a result of their mechanism of action and evolutionary development
- Correctly employed Bayesian approaches may be less burdensome
- Often the use of prior information may alleviate the need for a larger sized trial
- For more information please visit:
    - *Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials* at: https://www.fda.gov/MedicalDevices/ucm071072.htm

FDA 2010 Guidelines, cont.

- When an adaptive Bayesian model is applicable…
    - The size of a trial can be reduced by stopping early when conditions warrant
- Bayesian approaches to multiplicity problems may be advantageous
    - (multiple endpoints and testing of multiple subgroups)
- Bayesian methods allow for great flexibility in dealing with missing data

FDA 2010 Recommendations

- In the context of clinical trials…
    - An unlimited look at the accumulated data when sampling is of a sequential nature will not affect the inference
    - In the frequentist approach, interim data analyses affect type I errors
- The ability to stop a clinical trial early is important from the moral and economic viewpoints
- Trials should be stopped early…
    - Due to both **futility**: to save resources or stop an ineffective treatment
    - And **superiority**: to provide patients with the best possible treatments as fast as possible.

Summary