Regulatory Perspectives

Harvard Catalyst’s
Adaptive Clinical Trials Symposium

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Sponsor Responsibilities

- Develop a protocol that clearly lays out the “adaptive design”
  - “Prospectively planned” before data examined in an unblinded manner by any personnel involved in planning the revision
  - Details should be specified in the protocol

- Study monitoring
  - Assess and ensure quality of the study conduct and data

- Plan for preventing bias
IRB Responsibilities

- Before approving research, ensure that:
  - Risks to subjects are minimized through sound research design
  - Informed consent will be obtained from prospective participants
  - Adequate provisions for monitoring the data collected are in place to ensure participant safety

21 CFR 56.111
Investigator Responsibilities

- Ensure the IRB approved protocol is followed
- Timely reporting
Continuing Oversight

- What must the IRB review?
  - Changes to the protocol: “planned” vs “unplanned”

- What is the role of the DSM?

- What should be conveyed to participants?
Guidance

- FDA’s “Guidance for Industry: Adaptive Design Clinical Trials for Drugs and Biologics” (2010)