

# Costs, Timing, and Loss of Revenue Industry Sponsor's Perspective

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# General considerations (1)

- Current Clinical Research environment – Key Drivers
  - Increased complexity of product development
  - Increased duration of development programs
  - Increased size of programs – Large multi-center trials
  - Globalization (trials conducted in multiple countries)
    - Balancing the local versus global needs (including methodological issues)

# General considerations (2)

- Historical Perspective
  - 2001 AAMC-PhRMA forum on use of central IRBs
  - PhRMA May 2005 comments on FDA draft guidance on “Using a Centralized IRB Review Process in Multicenter Clinical Trials”
- Efficiency is a critical element
  - Reducing the burden of redundant reviews in multicenter trials
    - Initial review, periodic review, review of safety information
  - Other paradigms – Possibility of identifying best practices ?

# Costs

- Considered part of costs of research (overhead)
- Overall not significant compared to investments required to bring a new product to patients (PhRMA metrics – \$ 800 M – over \$ 1 B)
- Issue is efficiency, quality and timeliness rather than cost
  - Any improvement in the above would have a positive impact on product development, which would outweigh upfront/higher costs, if required

# Timing

- Rapidity of review is critically beneficial to Sponsors, but timing and quality of review are not mutually exclusive
  - Efficiencies gained by avoiding duplicative reviews should lead in improvements in both quality and timeliness
    - Reduced review load should lead to increased focus, and more rapid and thorough reviews
  - Multiple beneficiaries, including research participants

# Potential Revenue issues

- From the Industry Sponsor's perspective
  - Linked to efficiencies and timing
  - Equating timing of IRB review/delays to lost revenue probably irrelevant given the complexity of commercial product development process
- From the Institution's perspective
  - Possible loss of revenue from Industry Sponsored trials (how significant?)
  - Value of alternate revenue mechanisms (e.g., part of institutional overhead)?
  - Possibility of indirectly promoting alternate locations where IRB process is more efficient

# Food for thoughts

## Additional questions to ask:

- As an example, some countries are currently implementing Ethics Committees at the national level:
  - What are the cultural, infrastructural or legal barriers to such an approach in the US?
  - Are these barriers justified?
  - Does the current system provide full benefits to research participants in terms of additional protection?
  - In an increasingly global environment, what is the potential impact to the clinical research infrastructure in the US?
- What ideas could this conference generate to help identifying solutions that would:
  - Improve patient protection and,
  - be efficient and viable for the long-term?