THE USE OF ADAPTIVE DESIGNS IN AN NIH-FUNDED CLINICAL TRIALS ENVIRONMENT

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ADAPTIVE DESIGNS

Recently, there has been considerable research on adaptive designs (ADs).

Adaptive designs include the possibility of redesigning the trial based on interim results.

Group sequential designs are an important special case, but there are a number of different adaptations.

The rapid proliferation of interest in adaptive designs and inconsistent use of terminology has created confusion about similarities and differences among the various techniques.

ADAPTIVE DESIGNS

For example, the definition of an “adaptive design” itself is a common source of confusion.

PhRMA Working Group on Adaptive Designs (2006):

“By adaptive design we refer to a clinical study design that uses accumulating data to modify aspects of the study as it continues, without undermining the validity and integrity of the trial.”

“…changes are made by design, and not on an ad hoc basis”

“…not a remedy for inadequate planning.”

ADAPTIVE DESIGNS

However, before any adaptive design can be practically implemented, there are also logistical challenges that must be addressed.

Most of the available literature focuses on how these issues would be addressed in context of industry-sponsored trials.

Although some issues are the same, there are important distinctions in how these issues must be addressed in NIH-sponsored trials.

ADAPTIVE DESIGNS

This session will:

- Include descriptions of NIH-funded trials that have utilized an adaptive design
- Discuss the logistical issues the presenters believe must be addressed in order to utilize adaptive designs in this environment
- Discuss how the presenters have worked to overcome these logistical issues