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21 - Alzheimer's Disease

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Summary

The rapid proliferation of interest in adaptive designs, and inconsistent use of terminology, has created confusion about similarities and differences among the various techniques. This chapter focuses on some specific adaptive designs that have received the most attention to date. Although many adaptive designs employ the use of Bayesian statistical techniques, it is important to consider both Bayesian and Frequentist approaches to adaptive designs. Adaptive designs are generally well accepted and encouraged for early phases of drug development. For confirmatory trials, regulatory agencies will accept some adaptive designs but are cautious about others. A number of adaptive designs have been classified as 'generally well understood adaptive designs with valid approaches to implementation' in the FDA guidance document on adaptive designs. The major barriers to the implementation of adaptive designs in future clinical trial protocols are primarily logistical, rather than statistical.

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