

Title:

Power, sample size and adaptation considerations in the design of group sequential clinical trials

Author(s):

Tze Leung Lai and Mei-Chiung Shih

Technical Report number (Dept. of Statistics, Stanford Univ.):

2003-33

Date:

October 2003

Abstract:

A class of flexible and asymptotically efficient group sequential designs is developed herein for one-sided and two-sided tests of the parameter of an exponential family. Efficiency is measured in terms of the expected sample size and power function, under pre-specified constraints on the maximum sample size and Type I error probability. It is shown how these designs achieve asymptotic efficiency by adapting to the information about the unknown parameter during the course of the experiment. Moreover, they are very flexible and can circumvent the difficulties due to 'information time' versus 'calendar time' that arise in more complex settings such as time-sequential clinical trials comparing the failure times of two treatments.