

Optimal Sample Proportion for a Two-Treatment Clinical Trial in the Presence of Surrogate Endpoints

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Abstract

The use of surrogate endpoints is a very popular practice in medical research when true endpoints are expensive or only available after a long time. Here we obtain an optimal proportion of allocation among two competing treatments based on both true and surrogate endpoints. As the optimum true-surrogate sample proportion obtained by minimizing the variance of the estimated parametric function, e.g., the treatment difference, lies on a boundary in parameter space, we obtain cost optimized choices for these parameters. These are further used in a two-stage optimization for the proportion of allocation to the two treatments.