Financial management of a large multisite randomized clinical trial.

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Abstract:

BACKGROUND: The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) received five years' funding ($21 112 866) from the National Institutes of Health to compare carotid stenting to surgery for stroke prevention in 2500 randomized participants at 40 sites.

AIMS: Herein we evaluate the change in the CREST budget from a fixed to variable-cost model and recommend strategies for the financial management of large-scale clinical trials.

METHODS: Projections of the original grant's fixed-cost model were compared to the actual costs of the revised variable-cost model. The original grant's fixed-cost budget included salaries, fringe benefits, and other direct and indirect costs. For the variable-cost model, the costs were actual payments to the clinical sites and core centers based upon actual trial enrollment. We compared annual direct and indirect costs and per-patient cost for both the fixed and variable models. Differences between clinical site and core center expenditures were also calculated.

RESULTS: Using a variable-cost budget for clinical sites, funding was extended by no-cost extension from five to eight years. Randomizing sites tripled from 34 to 109. Of the 2500 targeted sample size, 138 (5.5%) were randomized during the first five years and 1387 (55.5%) during the no-cost extension. The actual per-patient costs of the variable model were 9% ($13 845) of the projected per-patient costs ($152 992) of the fixed model.

CONCLUSIONS: Performance-based budgets conserve funding, promote compliance, and allow...
for additional sites at modest additional cost. Costs of large-scale clinical trials can thus be reduced through effective management without compromising scientific integrity.

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