

ACCRUALMASTER: SOFTWARE FOR PLANNING AND MONITORING ACCRUAL RATES IN CLINICAL TRIALS

The most common reason why clinical trials fail is that they fall well below their goals for patient accrual. Researchers will frequently overpromise and underdeliver on the number of patients that they can recruit during the proposed time frame. The result is studies that take far longer than planned and/or that end with fewer patients than planned. This raises serious economic and ethical issues. We have developed a Bayesian model for accrual that will encourage careful planning of accrual rates as well as allow regular monitoring of accrual patterns during the conduct of the clinical trial. We have developed software in R that can show graphically the expected duration of the trial under initial planning estimates of accrual rates and that can adjust those accrual rates as the trial progresses by combining the actual accrual data with the prior beliefs of accrual. This software can be used by individual researchers, by Institution Review Boards during their continuing review of approved projects, and by Data Safety and Monitoring Boards during their interim analysis. We are working on extensions of the software to multi-center trials, to assessing the impact of refusal rates and losses due to exclusion criteria, and to non-uniform accrual rates (e.g., accrual rates in a trial expected to have a slow startup period). We are looking for support and collaborators to make the software available on a R server computer using a simplified front-end interface, to test the software prospectively in a series of clinical trials, and to support research on the extensions to new and important areas.

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