Abstract Title: Validation of a clinical trial accrual predictive model
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Describe the background of the problem: The costly and extensive process to drug approval highlights the need to streamline the drug pipeline process. In order for a clinical trial to draw scientifically sound conclusions, the study must meet its accrual goal. Dilts et al. reported that, at four comprehensive cancer centers, approximately 20-40% of trials will not accrue any subjects locally (Dilts, 2010). With increasing cost to conduct clinical trials, it is imperative to select trials rationally for local activation. We previously reported a novel predictive model with the outcome of anticipated accrual to be used when considering a prospective clinical trial at our center. Here, we present the results of the validation study.

Provide metrics or goals hoped to be achieved with the solutions to address the problem: We sought to validate a predictive model using factors known prior to study activation with the outcome of anticipated accrual that can be used when considering activation of a prospective clinical trial.

Describe the solutions or methods implemented: Eligible studies include treatment and supportive care intervention studies permanently closed to accrual between 10/2013 and 01/2015 at our center. Data abstracted from the clinical trials management system (OnCore, Forte Research Systems, Madison, WI) included: use of investigational drug, disease management team (DMT), use of local IRB, local start date, DMT accrual prediction value, actual total accrual, and clinicaltrials.gov (NCT) number. Abstracted from clinicaltrials.gov were protocol-specific data: number of national sites, national enrollment goal, national start date, and national date of expected primary endpoint completion. Studies were run through the model and actual accrual plotted against predicted accrual. Actual, team- and model-predicted subjects accrued; percent of trials meeting cut-off values; and model sensitivity and specificity were calculated.

Describe the outcome of the solutions implemented or show data representing a change whether positive or negative. Sixty-one trials met study inclusion criteria. Total accrual was 373 subjects (mean: 6.1±17.2); 16 (26.2%) studies had zero accrual, 23 (37.7%) accrued 88.7% of the total subjects. The model predicted accrual of 513 subjects (138% of actual) versus the DMT predicted accrual of 1111 subjects (298% of actual). The model correctly predicted whether a study would accrue 4+ subjects 75% of the time. Twenty-seven studies (44.3%) correlated perfectly at the category level. Model sensitivity is 70%; specificity is 78%. For the 17 studies not correctly categorized using a cutoff of four, nine (60%) would have been incorrectly opened (predicted 4+, <4 accrued) and six (40%) would have incorrectly not opened (predicted <4, 4+ accrued).

Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome. The identified national and local factors to predict clinical trial accrual at our center are valid, showing it to be an accurate, quick and valuable metric in assessing trial success as well as planning resource allocation. Further research includes national expansion of the model to cancer centers.