Predicting Accrual Success for Cancer Clinical Trials

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1. Background

Activating and supporting clinical research studies utilizes many resources. Sylvester Comprehensive Cancer Center (Sylvester) has developed a comprehensive feasibility assessment process that aims to identify potential stumbling blocks to activation, recruitment, trial conduct, etc. One area that has been traditionally overlooked is the ability of trials to meet stated accrual goals and, relatedly, to utilize resources efficiently. Between 2013 and 2023, only 38 percent of Sylvester trials – both interventional and non-interventional – were deemed to have accrued successfully, (i.e., they surpassed a threshold of 80 percent of their initial accrual goals).

2. Goals

Our goal was to develop a predictive algorithm to help identify clinical research studies that might be at risk for failing to meet accrual goals. We analyzed data for studies that opened and closed between 2013 and 2023 for criteria that can predict accrual success or failure. Due to the complexity of the analysis and the many variables that were available, we focused on studies that both opened and closed in 2022 and 2023 to identify an initial set of predictor variables for the algorithm.

3. Solutions and Methods

We developed a multivariate linear regression model to investigate the relationship between predictor variables and overall accrual. More than 20 different variables were assessed, including principal investigator (PI), site disease group (SDG), accrual target, and accrual progress post-study activation.

4. Outcomes

We found four factors significantly influenced overall accrual: the number of interventional treatment studies already open at the time of new study activation 1) with the same PI and 2) as part of the same SDG; and accrual at 3) 6-months and 4) 12-months post-study activation. The combined correlation coefficient for the four predictor variables was 0.86 ($p < 0.5$), a strong positive correlation.

5. Lessons Learned and Future Directions

Our initial analysis yielded a set of four predictor variables that strongly correlated with final accrual. Work is ongoing to expand the analysis to studies that opened and closed between 2013 and 2021, with an aim to identify additional predictor variables. We also recently began piloting the algorithm that incorporates these variables to test predictions of accrual success (or failure), applied at one-year post-study activation.