

First Accrual Within 70 Days of Opening Predicts Overall Trial Accrual Success

K. Hoy, A. Gerds, J. Chan, K. McCaffrey, E. Worthing, F. Arnold, L. Masar, M. Kilbane, H. Pounardjian

Case Comprehensive Cancer Center

1. Background

Low- and non-accruing trials consume limited resources while generating little meaningful output, resulting in increased costs and translational timeline for new biomedical discoveries. Comprehensive cancer centers normally use a reactive approach when addressing these studies. Trials that do not accrue at an acceptable rate are flagged for low accrual at 6- or 12-month intervals. This process requires lengthy follow-up and is based on the goals that the study team self-reports during start-up. This inefficient model of monitoring is time intensive and keeps low-accruing studies open for months before poor performance is discovered and mitigated.

In this project we looked to develop a straightforward early predictor of accrual success through the duration of a study. Multifactorial methods to predict and characterize low-accruing protocols have been described (Bennette 2015; Tang 2017). We aim to develop a simple, predictive metric that can identify unsuccessful clinical trials earlier in the study's life cycle. Our hypothesis is that trials that accrue the first participant in 70 days or less will be significantly more likely to reach their accrual goals.

2. Goals

- Characterize trials that will reach accrual goals
- Establish proactive metrics that can be used to identify which trials should receive resources

3. Solutions and Methods

- Share best practices across our consortium partners, ensuring all stakeholders share the same vision and goals
- Descriptive statistics and regression analyses on all trials open to accrual from 2007-2023 Q1

4. Outcomes

- 2183 trials were reviewed from 2007-Q1 2023
- 960 protocols accrued first participant in less than 70 days
- 790 protocols accrued first participant greater than 70 days
- 433 protocols had no accrual at the time of analysis
- Studies with accrual at >70 days average accrual 16, median 6, SD \pm 42
- Studies with 70+ days average 8, median 4, SD \pm 19
- Protocols with less than 70 days to first accrual had 100 percent higher average accrual and 50 percent higher median accrual

5. Lessons Learned and Future Directions

- Further analysis will examine trends across sponsor type, phase, data table 4 type