Decreasing the Time to Activation for Clinical Research Studies
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Problem Statement: To offer the best clinical trial options and to stay competitive with other centers, our trials need to open quickly. A typical trial has three levels of review: Department, Research Council (RC), and IRB/Privacy (PB). For industrial protocols, the contract also must be executed. This review process ensures that our Center opens high quality clinical trials (in study design, human subjects protections, scientific priority, resources). Inefficiencies can delay the time to activation (TTA): a full agenda, investigator delay, or poorly written consents. The TTA clock starts when a study is reviewed at the department and stops when the study opens at the IRB/PB including a fully executed contract. Prior to this initiative, our center’s TTA ranged from 37 days to over 365 days. Our primary goals: (1) expand our review capacity; (2) track every step of the review process in real-time; and (3) most critically, to decrease the overall TTA to a maximum of 90 days or less (except for IIT IND trials).

Methods: To achieve these goals, the following steps were required: increase in committee capacity, IRB/PB from one review committee to two committees, RC from one review committee to two committees, Protocol Priority Score (to ensure only protocols with a high score move forward), use of an electronic Protocol Information Management System in every clinical department protocol review committee through IRB and contracts/budgets reviews, Protocol Review Manager who tracks each protocol and provides assistance with the process, real time monitoring of all protocols via TTA Dashboard, and consent writing and training program. The project began in early 2013, and was fully operational in July 2013. We are now tracking every protocol at our Center on the dashboard from the time of initial review at the department level through IRB/PB and contract/budget execution. After implementing the TTA changes, we compared the trials that opened in the third and fourth quarters of 2012 and 2013 (before/after TTA initiative). These early results demonstrate a decrease in the TTA by 36% (median days reduced from 164 down to 105).

Conclusions: Industrial trials have nearly reached our goal of 90 day activation (median ~105 days). Through the real-time monitoring (via dashboard and manager), we are quickly able to identify delays and guide the protocol. Additional minor modifications will be planned as we continue to improve the review process.