Category: Clinical Trial Operations – Work in Progress

New Study Feasibility: Harnessing the Power of REDCap

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1. Background

Stanford Cancer Clinical Trials Office (CCTO) policy required the conceptualization and feasibility of new clinical trials to be captured in a New Trial Feasibility Form. Study feasibility review is essential for illuminating and resolving the intricacies and challenges of a proposed clinical trial at a finite level. This includes identifying locations of research, services and resources needed inside and outside the institution, funding methods, and distribution of staffing resources. If deemed feasible, trials will then move into the initiation phase. The previous New Trial Feasibility Form, in paper format, presented many operational challenges: lack of workflow for feasibility approval from managers; out-of-date questions; inaccessibility to form responses by upper management; and incompleteness of feasibility as seen by issues arising after the trial had opened.

2. Goals

To increase transparency and communication across the institution through: (1) visibility and forecasting of required study resources; (2) the creation of a feasibility workflow with managers and research staff; (3) providing a preliminary evaluation of workload distribution thereby creating strategic planning resources for management; (4) integration of OPAL feasibility scores into the assessment. Utilizing an electronic database will allow CCTO to easily collect and analyze study feasibility metrics including compliance, workload distributions, identify QI projects, and predict workforce needs.

3. Solutions and Methods

Launched on January 20, 2020, the web-based, PHI-secure, REDCap form and database are currently utilized by more than twenty Clinical Research Groups (CRGs) within the CCTO. Extensive review, updates and beta-testing was utilized to incorporate feedback from all entities across the institution. Field entries include fill-in text boxes, single & multiple choice responses, calculated fields based on entered data, document uploads and document downloads. The feasibility form can be completed by any research staff member, and once submitted, CRG managers must review and approve study feasibility within the database side of the form. As of March 3, 2020, fourteen (14) feasibility forms have been completed institution wide.

4. Outcomes

While further data is needed, Figure 1 depicts the recent launch of the Feasibility Form in REDCap on January 20, 2020. Figure 1 show moderate amenability with the new format: 66.67% compliance in February 2020, the first full month of use. Note that compliance in January 2020 is disproportional to CCTO Intake Submissions due to the mid-month launch, however, increased compliance is anticipated as 2020 continues.

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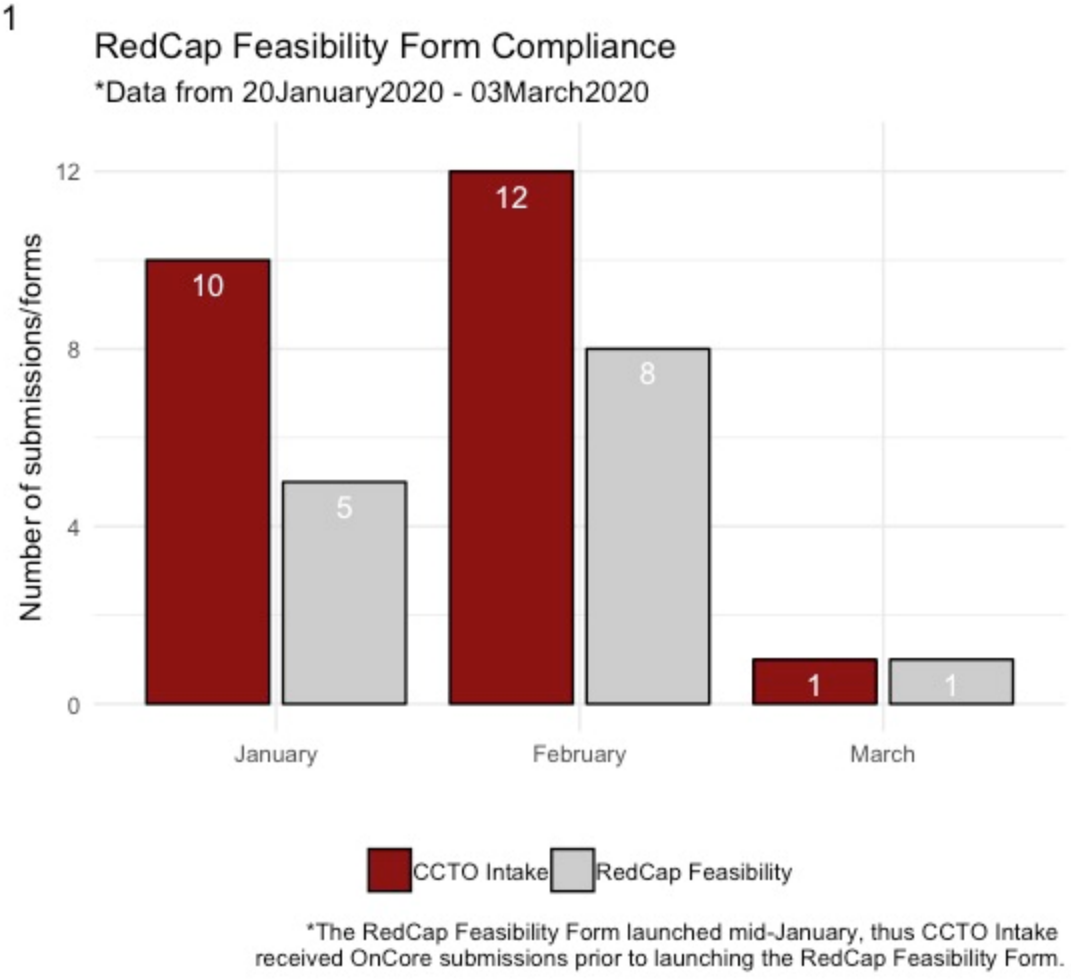
Figure 1



5. Lessons Learned

At the one-year benchmark, future analysis of the feasibility form submissions will include: (1) evaluation the preliminary versus actualized OPAL scores, which would allow the identification of significant differences in initial feasibility with accruing study protocol requirements, illuminating discrepancies and areas of focus to resolve; (2) investigating if the type of staff, PI Credentials, or CRG who completes feasibility forms for new studies associates with larger differences in initial versus final OPAL scores, thus showing areas of QI improvement; (3) analyses with other significant variables, e.g. time to complete feasibility, type of patient population being targeted with new studies, type(s) of proposed trials (Phase I – III, Industry vs. Investigator-Initiated), physical locations of research within the institution and issues therein, and trial funding diversity.