Objective

The primary objective of this quality improvement (QI) initiative was to improve Study-Start-Up (SSU) for complex investigator initiated clinical trials to < 150 days, and sponsor initiated or lower complexity trials to < 120 days. To achieve this, our multidisciplinary CTO team developed target timelines for each phase of SSU, then identified areas for improvement and methods by which we could target those barriers to improve SSU efficacy.

Background

Shortening the SSU timeline is a multifaceted and largely heterogeneous problem across CTO’s. In addition, there is very little published research regarding specific barriers to SSU, preventing identification of umbrella solutions from literature sources alone. Therefore, our multidisciplinary team of CTO stakeholders (CRC), registered nurses (RN), regulatory specialists (RS), program managers (PM), administrative leadership, and the Cancer Research Translational Initiative (CRTI) team conducted an internal root cause analysis (RCA) focused on critical activities in the SSU process. Several areas for improvement were identified. Presented here are recognized opportunities for change, critical time points, target timelines, collaborative process improvement strategies, and our evaluation metrics.

Cross-Functional Working Groups:
- Reducing SSU Timelines: Collaborate with internal and external CTO stakeholders to recommend and implement methods to reduce SSU
- CRTI: Translational mechanism connecting interdisciplinary teams across the Cancer Center and University to move translational studies from bench to bedside
- Campus Wide Collaborators: Clinical Research Support Center: 360 feasibility review
- Health Information Technology (HIT): Epic order production
- Sponsored Projects Administration (SPA): Budgets and Contracts
- Internal Review Board (IRB): Methods to reduce review timeline
- Disease Focused Interdisciplinary Site-Specific Care (ISC) Teams: Faculty lead disease-focused groups to prioritize studies, identify & eliminate barriers, etc. including clinical and research representation.
- Opening the Right Studies: Establish guidelines for the CTO to follow when opening a site to ensure successful implementation and conduct.

Process-Improvement

Initiatives:
- Established best practices with expected timelines for typical SSU tasks. Projects identified as having the greatest potential impact are outlined below.
  - Established Timelines: Each new study is assigned a project timeline for major milestones during start-up.
  - Contingency Planning: Implemented a contingency plan to obtain required information for regulatory applications if the investigator planning meeting is delayed.
  - Sponsor FAQ: Assembled frequently asked questions from sponsors to provide SOPs and site information up front.
  - Timely Document Preparation: Optimized timing of regulatory documents assembly, with the goal to prevent downstream delays due to pending signatures.
  - Optimized Timing of Ancillary Reviews: Improved timing of departmental ancillary reviews which require sign-off prior to IRB review.
  - Engagement of Stakeholders Outside CTO: Established mechanisms for setting priorities for efforts performed outside of the CTO.
    - HIT: Partnered with HIT to improve timely Epic® order builds and production.
    - SPA: In collaboration with SPA developed standardized budget assumptions, built budget tools, and established labor guidelines to reduce time in negotiations.
    - IRB: Worked with IRB leadership to accelerate review timeline.
  - Improved LOI Template: Enhanced the draft letter of intent (LOI) template to reduce time spent in the budget and negotiations phase of SSU.
  - Targeted Preventable Amendments: Investigator Initiated Trials: Leveraged expertise of experienced Clinical Research Coordinators when developing local protocols to prevent delays caused by protocol amendments during start-up.
  - Sponsored Studies: Changed our policy to request holds on amendments that can wait until after initial IRB approval to avoid retraction and revision of the initial application.

Evaluation Metrics:
- Biannual evaluation of timelines
- Review of IRB specific time points
- Quarterly review of working group project specific metrics and progress towards shared goals

Key Insights

- Collaboration: Integration of clinical and research teams for real-time communication, transparency, and standardized practices were fundamental to our collective improvement in SSU timelines.
- Development of cross-functional working groups
- Development of organized ISC team structure as a multidisciplinary venue to discuss trial portfolios by disease
- Technology: Consideration of advanced technology based platforms for real-time communication between clinical staff and within our community of research staff.
  - Grant for SmartSheet®
  - Portable workstations for timely, remote communication
- Goal Alignment: Establishment of an agreed upon SSU timeline was a pivotal milestone in our progress towards shortening SSU.
- Transparency: This extensive CTO-wide initiative also heightened our regard for transparency as we sought to align our shared paths.