Masonic Cancer Center
University of Minnesota
Comprehensive Cancer Center designated by the National Cancer Institute

Improving Study Start-Up Timelines: A Comprehensive, Multidisciplinary, Process-Improvement Initiative

NCI Designated Comprehensive Cancer Center

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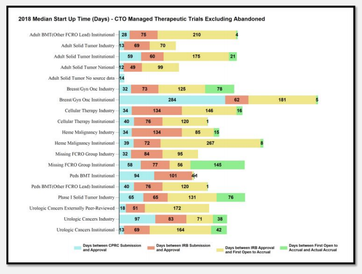
Objective

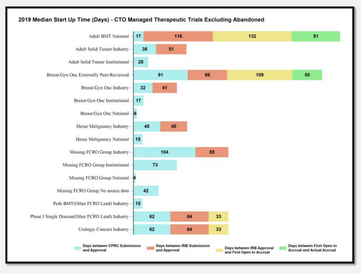
Objective: The primary objective of this quality improvement (QI) initiative was to improve Study-Start-Up (SSU) for complex investigator initiated clinical trials to < 150 days, and sponsor initiated or lower complexity trials to < 120 days. To achieve this, our multidisciplinary CTO team developed 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

Background: Shortening the SSU timeline is a multifaceted and largely heterogeneous problem across CTO's[1]. 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 clinical research coordinators (CRC), registered nurses (CRC-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.



2018 Median SSU (Days)



2019 Median SSU (Days)

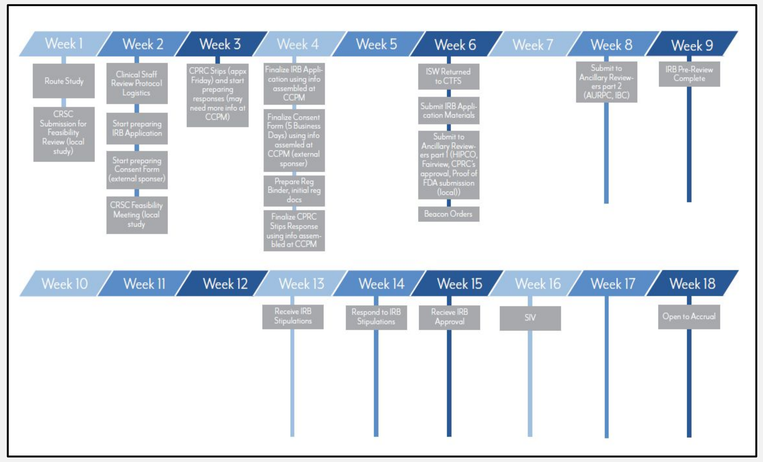
Approach

Approach: We discovered several barriers to efficient study activation. Once identified, focus groups were created to set goals and implement quality improvement initiatives targeting each barrier. Groups consisted of collaborators from a wide cross section of our CTO, allowing team members to provide expertise based on their unique practice ontology and experiential knowledge base.

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 trial to ensure successful implementation and conduct.

Process-Improvement



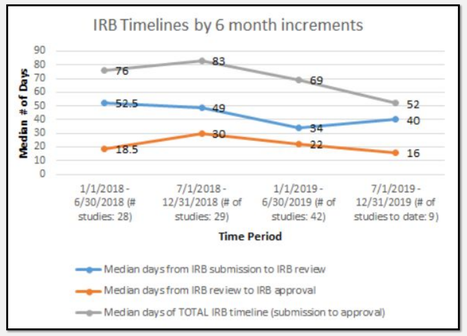
Goal Timeline for Study Activation (120 Days)

Initiatives

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.
- **Leveraged Technology:** Implemented FDA IND/IDE submissions, electronic signatures for regulatory documents, and invested in Electronic Data Capture *Part 11* compliant technology.

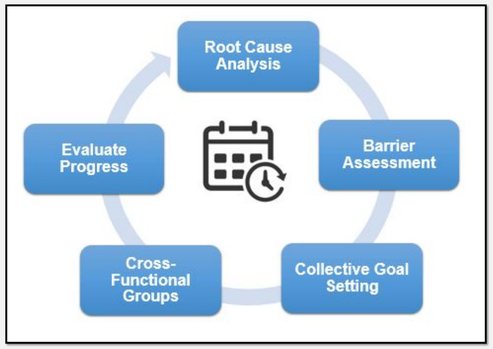
Evaluation



Median Change IRB Timelines: 01/01/2018-12/31/2019

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



Implementation and Evaluation Cycle

Key Insights

Lessons Learned:

- **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.

References

Choi YJ, Beck SH, Kang WY, et al. Knowledge and Perception about Clinical Research Shapes Behavior: Face to Face Survey in Korean General Public. J Korean Med Sci. 2016;31(5):674-681. doi:10.3346/jkms.2016.31.5.674