Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) - Work in progress

People, Not Just Processes: Reimagining the Study Start-up Lifecycle

B. Scruggs, N. Khadke, L. Farnon, J. Gallagher, K. Herman

Sidney Kimmel Comprehensive Cancer Center at Jefferson

1. Background

The Sidney Kimmel Cancer Center (SKCCC) Clinical Trials Office (CTO) originally utilized a localized, disease-group-led Study Start-Up (SSU) model to ensure deep therapeutic alignment within specialized research teams. While this structure prioritized disease-specific nuances, the subsequent transition toward a centralized team—driven by an institutional need for operational efficiency—revealed a Centralization Paradox. This paradox suggests that while centralized frameworks improve structural metrics, success is ultimately dependent on managing the human variable: the diverse personalities, legacy workflows, and institutional resistance inherent in shifting away from a localized culture.

2. Goals

To optimize the trial activation lifecycle, SKCCC CTO aimed to move away from a linear, siloed workflow toward a centralized, high-accountability SSU model. The primary goals were to:

- Synchronize parallel workstreams (Regulatory, Finance, and Clinical) rather than following a sequential process
- Harmonize disparate work styles across various Multidisciplinary Disease Groups (MDGs)
- Reduce administrative fatigue for clinical staff by providing a dedicated point of accountability

3. Solutions and Methods

To initiate this operational shift, the SKCCC CTO implemented a centralized SSU team designed to transition the trial activation lifecycle from a linear path to a parallel progression model. While the initial implementation began with subtle whispers of organizational change, the inherent complexity of the human variable proved significantly more difficult to navigate than anticipated. This friction necessitated a pivot toward a transparent strategy designed to humanize the transition through intensive stakeholder alignment and continuous feedback loops. Currently, the team is standardizing operational frameworks to harmonize diverse work styles and communication preferences across MDGs. By prioritizing relationship-building alongside process design, the CTO balances centralized efficiency with the unique clinical nuances of each disease team to establish a sustainable, performance-focused environment.

4. Outcomes

While comprehensive quantitative analysis is currently underway – comparing metrics from the six months prior to and following SSU implementation – early implementation of the centralized SSU model has demonstrated a marked shift in operational momentum. Anecdotal evidence suggests that the transition to parallel workstreams has effectively addressed long-standing bottlenecks; specifically, trials that previously faced significant delays or stagnation are now moving forward with problem-resolution timelines reduced from weeks or months to just days. These preliminary results indicate that the

accountability and the team's focus on stakeholder alignment are successfully bridging the gap between administrative requirements and the unique needs of the multidisciplinary disease groups.

5. Lessons Learned and Future Directions

Structural change requires a solutions-driven leadership approach that prioritizes transparency over whispers. We learned that managing the human variable requires mastering multi-modal relationship management—using instant messaging, email, and targeted meetings to foster trust and reduce fatigue. Future initiatives include a centralized SSU dashboard for real-time, data-driven bottleneck identification, and evolving the team into a single point of contact for all internal and external start-up inquiries. By investing in professional development that balances centralized efficiency with clinical nuances, the CTO aims to reduce time-to-activation and establish a sustainable, results-oriented culture that aligns institutional workflows with the specific needs of the research mission.