

Novel CTMS Task List Implementation to Expedite Startup, Streamline Communication, and Facilitate Process and TTA Optimization

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1. Background

Time to Activation (TTA), the duration from Scientific Review Committee submission to open to accrual status, is a defining metric for cancer centers: minimizing it, without compromising compliance or the bottom line, is paramount to maximize the efficiency of the study startup process. The Lombardi Clinical Trials Office (CTO) and the Centralized Clinical Research Operations Office (CROO) partner to continuously explore new ways to improve TTA.

Previous analysis into the largest components of Lombardi Comprehensive Cancer Center's (LCCC) TTA revealed that between 5 and 15 percent is attributable to communication issues and extraneous lag time during task handoffs. A time-burden analysis revealed startup staff spent 12 to 30 percent of each day sorting and addressing emails, leaving less time for startup tasks.

2. Goals

- Reduce internal startup-related emailing
- Reduce communication inconsistencies
- Minimize task hand-off periods
- Reduce TTA by >15 percent

3. Solutions and Methods

OnCore, LCCC's clinical trials management system (CTMS), can display customized lists of tasks for each study shell. These task lists pull from a study-specific staff list in OnCore to auto-assign individual items, generate relative task due dates based on milestone dates entered, facilitate the simultaneous storage and sharing of primary study documents that are not already a part of the investigator site file (ISF) maintained by the startup regulatory team (e.g., initial budget and contract drafts and calendar schema), and house important communications and status updates. The Study Activation Coordinator (SAC), a position designed to focus on optimizing TTA, created comprehensive task lists covering all pre-activation steps along with a set of guides explaining usage and best practices. The SAC oversaw implementation and facilitated integration into the startup management flow cross-departmentally, beginning April 2023.

4. Outcomes

Task list implementation removed the need for approximately 80 percent of internal email traffic pertaining to study startup and cut the average task handoff time in half to 26 hours. Studies submitted to the SRC in 2023 activated, on average, 30 percent quicker than studies submitted to the SRC in 2022, with that number rising to 49 percent if only studies submitted from April onwards are considered. After deploying task lists, task handoffs only account for between 2 and 6 percent of the TTA for any given study, an average improvement of 6 percent. TTA improvement between 2022 and 2023 was accompanied by a reduction in studies submitted to the SRC of only 1.5 per month, on average, indicating that the reduction in communication and TTA cannot be attributed to a reduced study to staff ratio.

5. Lessons Learned and Future Directions

Task lists alleviated startup pain points and allowed dedicated study start-up staff to focus on tracking and improving negotiations, expanding study offerings, and other future growth initiatives including an expedited startup program. Expansion to incorporate tasks belonging to clinical operations team staff is in the pilot phase and will roll out in Q2 2024, with the goal of further reducing email traffic. Though not originally posited as a benefit, the transition to task lists from email-centralized tasks facilitated better consistency during staff turnover or extended out of office periods and allowed others to easily view statuses, access materials, and request assistance between departments.