Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) – Completed Project

Implementing a Team-Based Approach to Phase I Data Entry for Improvement of Data Timelines

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1. Background

Timeliness for data entry and query resolution is an important aspect of every clinical trial and is particularly emphasized when working with industry sponsors. Sponsors utilize queries in their Electronic Data Capture (EDC) systems to confirm data, explain discrepancies, or ask clarifying questions to sites. At the University of Illinois Cancer Center, these queries are answered by Data Coordinators (DC). Each DC is responsible for their own disease sites and the trials available to those diseases, with data entry being a DC's most important role. Until recently, Phase 1 trials were classified as their own disease site, with one DC being responsible for the data entry of all Phase 1 trials. As our Phase 1 portfolio expanded and enrollments increased, it became clear that these studies were more complex and demanding than previous disease site portfolios. A shift was necessary in our workflow to accommodate the increase in data entry and query resolution, as well as re-balance portfolios to decrease DC burden.

2. Goals

- Establish a new workflow to improve timeliness in data entry and query resolution for Phase 1 trials
- Decrease DC burden through a more even spread of Phase 1 patients across the DC team

3. Solutions and Methods

As Phase 1 trials often encompass several disease sites, the decision was made to dissolve the "Phase 1 DC" and instead distribute individual patients to DCs based on their disease site. Maintaining the same disease site assignments as our regular workflow allowed for an easy transition to the new system and redistributed the overwhelming workload of a single DC to multiple team members.

This process also involved establishing a "Lead Phase 1 DC" who was responsible for distributing patients based on disease sites to the correct DC. They also oversaw query volumes and communicated delinquent data to DCs, which proved vital during the transition phase to this new workflow.

4. Outcomes

Our workflow change was implemented in June 2025. One of the biggest indicators of change was the number of queries we received from sponsors, with one industry sponsor giving us the largest amount of query information to utilize. We saw a 23 percent decrease in queries when comparing data from before the workflow implementation to after indicating the quality of data being entered increased. There was also a 44 percent decrease in the median number of days queries were open. This decrease is also significant, as it lowered the average number of days a query is open from nine to five, achieving our institution's policy for query timeliness.

5. Lessons Learned and Future Directions

Transitioning our Phase 1 studies to a more team-centered approach on the DC side has not only enabled us to spread the increasing burden of Phase 1 trials but has also increased data timeliness and overall quality. As a team, we can more confidently tackle both complex data and queries, enabling us to better meet and exceed data standards and timelines. This more organized and team-centered

approach is something we would like to expand on, potentially exploring the implications in our established disease sites as accruals continue to rise.