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

Reducing NCTN Data Delinquency Through Structured Accountability and Centralized Monitoring

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1. Background

Timely submission of electronic case report forms (eCRFs) is critical to maintaining regulatory compliance, patient safety, and data integrity within National Cancer Institute (NCI)'s National Clinical Trials Network (NCTN) trials. Participating institutions are expected to meet established timeliness benchmarks, and sustained data delinquency places institutions at risk for increased audit scrutiny and may influence continued participation in cooperative group clinical trials. Despite use of Medidata Rave, the standardized electronic data capture platform for NCTN trials, persistent data backlogs remain a common operational challenge across multi-site oncology networks. At the Stanford Cancer Institute Clinical Trials Office, routine monitoring during the baseline measurement period demonstrated a sustained average backlog of 118 delinquent eCRFs, reflecting systemic workflow variability and limited cross-group accountability.

2. Goals

The primary aim was to reduce delinquent NCTN eCRFs from a baseline average of 118 to 90 or fewer. Secondary aims included strengthening cross-functional accountability, increasing staff engagement in data monitoring processes, and establishing sustainable workflow mechanisms to support timely data submission.

3. Solutions and Methods

An Evidence-Based Quality Improvement (EBQI) initiative was implemented using Deming's System of Profound Knowledge and iterative Plan-Do-Study-Act (PDSA) cycles. The intervention formalized structured use of the Clinical Trials Support Unit (CTSU) Data Quality Portal dashboard to provide real-time visibility of expected and delinquent forms. Structured staff training on dashboard access and interpretation was conducted during NCTN meetings to support adoption.

A standardized biweekly email notification process was implemented, requiring acknowledgment and ownership confirmation of overdue forms. Leadership oversight was reinforced through structured reporting and integration of timeliness benchmarks into routine communications.

Outcome measures included total delinquent eCRFs, forms more than 90 days overdue, and institutional form timeliness benchmark metrics. Process measures included acknowledgment response rates to delinquency notifications. Statistical process control methodology, including Individuals and Moving Range charts, was used to evaluate variation and detect special cause signals.

4. Outcomes

Following the six-month implementation period, a sustained centerline shift was observed in the primary outcome measure. The mean number of delinquent eCRFs decreased from 118.8 to 86.6, representing a 27 percent reduction and statistically significant special cause variation. Courtesy email acknowledgment rates improved from approximately 42 percent to as high as 80 percent, reflecting increased staff engagement and accountability. Although institutional form timeliness benchmark metrics did not demonstrate an immediate sustained shift during the project period, the reduction in

delinquent forms represents meaningful operational improvement and strengthened regulatory readiness.

5. Lessons Learned and Future Directions

Structured accountability processes, formalized dashboard utilization, and leadership integration can significantly reduce data delinquency within large, multi-group oncology research portfolios. Institutional timeliness benchmark metrics may require sustained longitudinal improvement due to cumulative and study-level reporting structures; however, consistent reductions in delinquent forms strengthen audit preparedness and reinforce a culture of timely data submission. Embedding centralized monitoring, standardized email notifications, and transparent performance review into routine workflows established a scalable and sustainable operational model. Future efforts will prioritize resolution of long-standing (>90-day) delinquencies and evaluate the long-term impact of sustained accountability interventions on institutional benchmark performance.