Category: Clinical Trials Operations - Work in Progress

Connecting the Chain – Part Two

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1. Background

There is considerable redundant work being performed today at both cancer centers and trials sponsors as a result of a lack of systems and data integration both within cancer centers and their related hospital Electronic Medical Record systems and Clinical Trial Management Systems as well as between cancer centers and trial sponsors. In a 2019 AACI-CRI Poster Session, we described a project in which we were able to reduce the time required for trial data collection by approximately 50% on three studies piloted by pulling data directly from the source medical record system into the electronic data capture (EDC) system. In this follow-up poster session, we will drill down on specific aspects of data collection where time and costs savings are achieved; the types of visits and studies that can particularly benefit; benefits related to facilitating access to unstructured data in the EMR; and other benefits such as easier source data verification and reduced data queries.

2. Goals

The key metrics we will focus on are a) time and cost savings by visit type, b) differences across study types (e.g. Phase I, II, and III), and c) other benefits in such areas as reduced queries.

3. Solutions and Methods

KUCC implemented a clinical trial fulfillment solution that integrates EMR data, its local clinical trial management system and related operations, and a sponsor's EDC system. The solution automates multiple aspects of clinical trial operations for study teams at the site; then leverages EMR data to populate case report forms directly into our local clinical research management system; then in turn electronically push the case report form data directly into the sponsor's EDC system.

4. Outcomes

The major finding of the project is multiple hours of time savings for study coordinators to complete study data requirements on patient visits in this sponsor-funded proof of concept. For each study tested, the time savings was significant. For one study, the average time savings for one screening visit was about four hours. The time savings for other recurring visits was about two hours per patient per visit. In addition, there were fewer queries and improved capabilities for source data verification.

5. Lessons Learned

The lesson learned is that significant time savings can be achieved through integration of EMRs, local clinical trial management systems, and sponsor EDC systems. The future direction, now that the proof and concept is complete, is to scale the solution and bring in other cancer center and study sponsors collaborators to both improve and benefit from the solution.