Category: Investigator Initiated Trials – Work In Progress

The Sample Collection and Tracking Process for Multisite Investigator-Initiated Trials

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1. Background

Correlative samples are an important component of many trials. They often contribute to the trial objectives and end points used to make important scientific discoveries in oncology research. However, these samples can often be difficult to track even in a single-center trial. After samples are collected, they often change hands many times before they are analyzed and/or sent for long-term storage. The process complexity increases exponentially with the addition of each site and each processing and/or analyzing laboratory. Currently, there is not an efficient system for tracking the location of these samples at any given time for studies where Indiana University is the lead site. We rely exclusively on sites to inform us when specimens are shipped or on labs to let us know when they receive samples. FedEx tracking is used for institution-to-institution transfers however, this does not allow for internal tracking between labs on the same campus. This can leave much room for error including misplaced samples.

2. Goals

Ability to know the location of specimens at any given time through a centralized online system.
Avoid future deviations or decrease deviations and the number of misplaced samples by identifying lost specimens in real time, which would increase the chances of these samples being located.

3. Solutions and Methods

Propose using Biospecimen Management (BSM), an application within OnCore™ is a web-based, Clinical Trial Management System developed by Forte, Inc. In conjunction with BSM propose using BarTender, a barcode label software, which will to connect to BSM and extract data to print study-specific barcoded specimen labels. The barcodes will be scanned, using a hand-held barcode scanner, tracking all samples from collection through final storage location/analysis. At any given time, the exact location of a specimen can be viewed in BSM.

Training sites and labs on proper usage of labels and the barcode scanners will be imperative. The logging and tracking of samples within BSM will need to be reviewed on an ongoing basis as well as reaching out to the sites or labs as soon as misplaced or mishandled specimens are discovered.

4. Outcomes

While this system is currently used locally at Indiana University for a few select labs it has not been utilized in the Clinical Trials Office or in the multisite setting. This idea has just been proposed. Indiana University Clinical Trials Office is currently researching costs associated with using such a tracking system as well as advantages of using in the multisite setting. Once the equipment, which includes a barcode label printer, BarTender license, barcode labels, and barcode scanners, are purchased it can be implemented for multiple projects. Therefore the overall cost can be minimized when distributed among the many projects.

5. Lessons Learned

We plan to pilot this system on a single study. Once the process has been refined we can use this institution-wide and in the multisite setting. This change has the potential to make the data collected from the samples stronger allowing the objectives and end points to be met effectively making the analysis more accurate and the science more beneficial.