Category: Cross-cutting Innovation and Collaboration – Work in Progress

Papers & Spreadsheets & Calls, Oh My!: Where Sample Data Falls Through the Cracks

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1. Background

Specimen data capture is dangerously inconsistent across clinical trials. Sponsor-provided requisitions are not universal and typically do not capture all inputs required for full chain of custody and proof of sample integrity within lab manual specifications. Additionally, while workflows across cancer center institutions may differ, clinical trial data capture is not currently robust or frequent enough to encompass the variability in workflow across organizations. Inconsistent tracking tools among sponsors result in increased site staff time, cost, and efforts that are challenging to capture, along with risks of less favorable patient experience.

2. Goals

The goal was to review logistical concerns of data capture along the patient specimen journey and determine critical impact points, variability among requests, and correlative distribution within local and network sites. Review of time spent on supplemental training materials to capture additional sponsor requested data was also conducted and the distribution of additional sponsor requests outside of the budgeted lab manual time points were obtained. Confirm consistent impact criteria and process stability within the local and network sites.

3. Solutions and Methods

Clinical trial protocols and laboratory manuals are reviewed at study start up for feasibility, and logistical concerns are addressed during start up. All studies follow a universal specimen and kit tracking workflow implemented by UPMC Clinical Research Services, independent of sponsor required data capture. Flow diagrams were created to show full patient specimen journey. Site supplementary logistic training materials were created and sent to site staff for studies outside of typical routine workflows. Excessive internal and external shipment requests outside of the agreed upon budget were monitored. A standardized tracking system for specimens and batch shipments was used to trace all impact points and data harmonized with use of Slope for kit supply within the disease centers and community network.

4. Outcomes

Several impact points of data integrity were observed throughout the flow diagram, regardless of where the samples originated from or clinical trial in which the patient was on. The outcome of laboratory staff processing specimens and calls to resolve queries were decreased due to universal tracking independent of sponsor requests for and specimens. Queries independent of standard requisition information were able to be addressed by departmental staff due to strict sample oversight. Process and Policy changes were implemented based on data review of protective measures and ability to address additional questions not captured within provided source documents.

5. Learned and Future Directions

Multiple methods can capture data, yet a singular input point would eliminate significant time spent tracing independent data. Most sponsor provided source forms or database capture fields lack necessary fields required for proper analysis, which forces a universal tracking tool requiring modern adaptable solutions for site needs. Linking the input point to destination output site would increase quality, timeliness, and allow for harmonized groups to work with each other. Sites and sponsors need

to consider implementation of robust and consistent sample tracking with data capture methods to streamline workflow, comply with federal standards, strengthen adaptability for clinical trial specimen complexity, and protect from fault in specimen integrity.

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