Paper Reqs, Spreadsheets and Calls, Oh My!: Where Sample Data Falls Through the Cracks

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Goals

- To review logistical concerns of data capture on the sample journey.
- Determine critical impact points, variability among sponsors, and correlative distribution within local and network sites.
- Review frequency and staff time spent on additional sponsor requests outside of the budgeted lab manual.
- Confirm consistency within the local and network sites, regardless of complexity.

Background

Specimen data capture is inconsistent amongst clinical trials.

Sponsor provided requisitions are not universal and typically do not capture input required for proof of sample integrity within lab manual specifications.

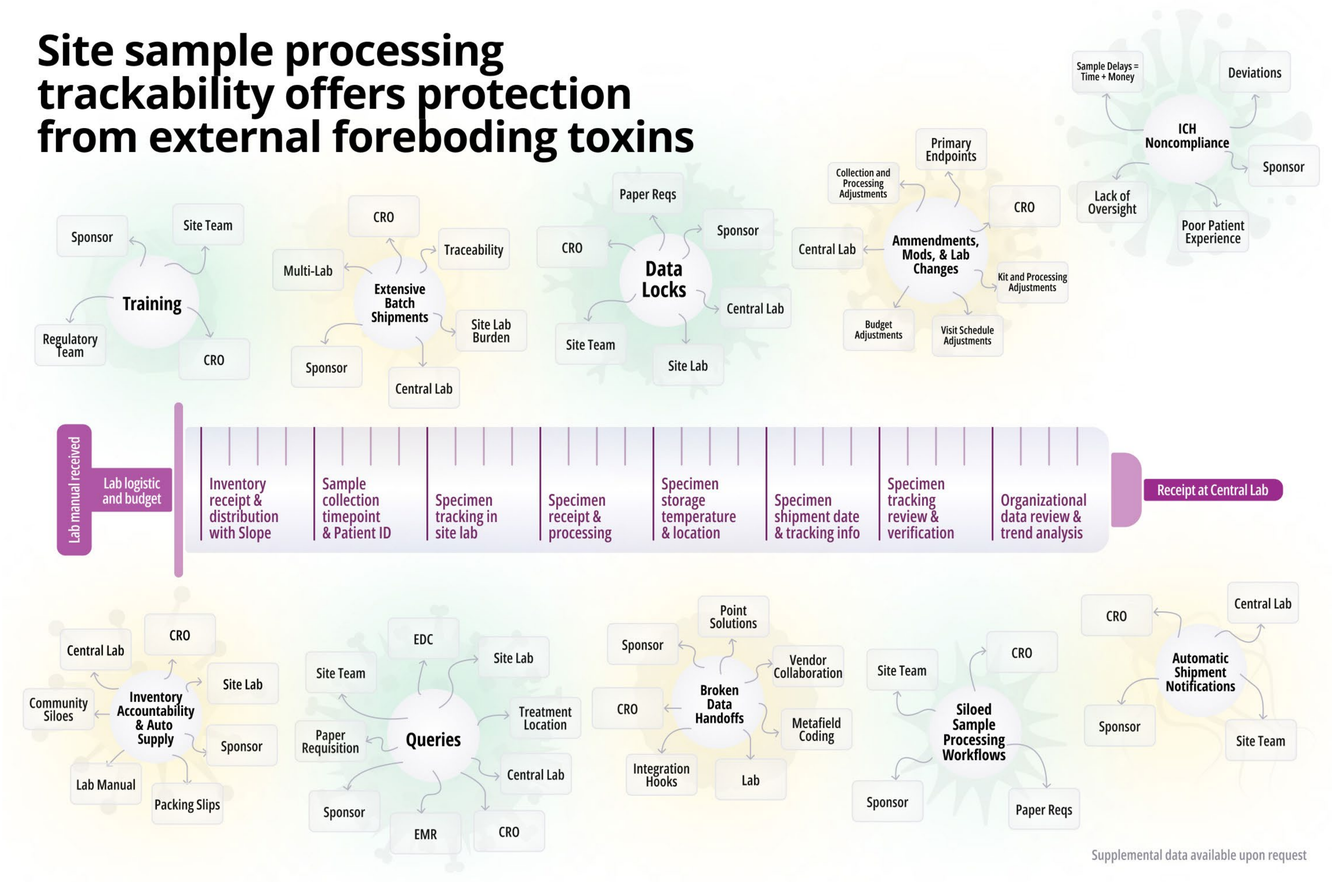
Workflows across cancer center institutions may differ, yet clinical trial data capture is not robust enough to encompass the variability in workflow.

Inconsistent tracking tools among sponsors result in increased site staff time, cost, and efforts that are challenging to capture.

Solutions and Methods

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

Data



Supplemental data available upon request

Outcomes

Several data integrity impact points were observed throughout the flow diagram, regardless sample origin or the clinical trial in which the patient was enrolled. The outcome of time spent from laboratory staff processing specimens for calls to resolve queries were decreased due to universal tracking independent of sponsor requests for 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.

Lessons Learned and Future Outcomes

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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