Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) - Work in progress

Customizing Enterprise Biobanking Software for Clinical Trial Management to Improve Efficiency

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1. Background

Clinical trial biospecimen management has historically operated outside of standard of care workflows, relying on manual schedule tracking and specimen databases. In 2022, NYU Langone Health Perlmutter Cancer Center (PCC) Clinical Trial Office (CTO) integrated Epic electronic medical record (EMR) with LabVantage, an enterprise laboratory information management system (LIMS) software, successfully streamlining research biospecimen collection workflows to align with standard of care lab draws. The integration leveraged existing Epic schedulable order workflows to create automated research patient visit calendars in LabVantage, fulfilling one aspect of streamlining biospecimen management. However, downstream documentation and maintaining a biospecimen database remained inefficient. A FileMaker pro database tracked aliquot vials using manual data entry to record collection, processing, storage, and distribution. Operational time studies identified database entries as the primary bottleneck, with a mean time of 11 minutes per entry and delays averaging 60 days (median delay of 14 days) from specimen collection to database entry. These delays caused inaccurate freezer inventories, difficulty locating specimens, time-consuming inventory quality checks (QCs), difficulty resolving sponsor queries, and delayed biospecimen activity metric reporting—impacting growth projections and resource allocation.

2. Goals

The project aims to replace the existing FileMaker Pro specimen database with a novel clinical trial specimen management platform within LabVantage. The platform would enhance efficiency by reducing data entry time, enabling real-time recording of research visits and specimen collection data, and effectively eliminating delays in maintaining up-to-date specimen records, freezer inventories, and activity metrics.

3. Solutions and Methods

In 2024, we began development with LIMS LabVantage customization. Project requirements included:

- Generate trackable specimens based on pre-defined clinical trial protocol parameters and associate them to existing patient-specific Epic appointments and orders
- Leverage existing demographic and appointment information from Epic research patient visit calendars
- Customize data capture fields for clinical trial lifecycle tracking (third-party laboratory identifiers, shipment conditions/tracking, and sample custody transfers)
- Record internal laboratory chain-of-custody and specimen processing statuses

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- Optimize electronic freezer storage inventory functionalities
- Enhance specimen reporting for dynamic metric capabilities

4. Outcomes

In 2025, customizations were implemented in LabVantage that allow staff to generate trackable specimens from existing patient research visits. Patient demographic, appointment, and protocol-specific specimen parameters are pre-filled during specimen receipt and processing in the research laboratory. Additional fields were created to capture shipment/distribution details, central lab requisition identifiers, and internal chain-of-custody tracking. The PCC Manhattan team is currently piloting this workflow with investigator-initiated trials. Preliminary staff surveys show a 36 percent decrease in data entry time per specimen compared to FileMaker and a 98 percent decrease in time from specimen collection to data entry, with a maximum delay of one day—demonstrating real-time specimen data capture with this system.

5. Lessons Learned and Future Directions

Reliable biospecimen management and lifecycle tracking is feasible and crucial for ensuring high-quality, reproducible research, sample integrity, and operational efficiency. Streamlining high-volume clinical trial specimen management requires a system that integrates patient demographics, appointment information, and enables real-time data entry. Next steps for this project include training and implementing workflows across all NYU Langone Health Cancer Center campuses for all clinical trials. Future projects include patient-specific study tracking with automated email notifications for research visit scheduling, bi-directional integration with Epic EMR for real-time data capture at the point-of-care, and enhanced reporting with dashboard features for comprehensive and accessible clinical trial biospecimen activity metrics.