Optimizing Biospecimen Workflows: Development of a Functional Clinical Trial Kit Inventory System Utilizing Enterprise Laboratory Information Management System (LIMS) LabVantage

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1. Background

Clinical trial sponsors provide protocol- and visit-specific biospecimen collection kits that are noninterchangeable with a short shelf life, making the maintenance of adequate and accurate inventories challenging. Before 2018, the Research Biofluid Management Unit (RBMU) of the Clinical Trials Office at NYU Langone Health (NYULH) Perlmutter Cancer Center (PCC) lacked a functional kit inventory using only 500 square feet (sf) of shelving in a 200 sf room. Excel was used to track quantities, expiration dates, and locations. Inaccurate inventories lead to over-ordering to compensate for missing supplies. Time from expiration to destruction was >6 months, leaving kits on shelves taking up space. Time from kit delivery to storage was >12 months due to lack of space to unpack boxes. Storage conditions were hazardous, and staff spent hours searching for materials, leading to a delay in locating kits for trial activations.

2. Goals

By customizing LabVantage, an enterprise laboratory information management system (LIMS), in collaboration with NYULH MCIT, we aimed to design a user-friendly inventory program that would allow quick input of kits to reduce the time from delivery to storage to <7 days, reduce the time from expiration to destruction to <30 days, and increase accuracy to establish off-site storage and avoid misplaced supplies.

3. Solutions and Methods

Development of a clinical trial inventory system using LIMS LabVantage began in 2017. Requirements included classifying kits by protocol, cohort, and visit; creating a one-to-many relationship between kits and time points; notifying of low quantities and expiration in real time; and recording locations. Kits are linked to patient visits and quantities are adjusted in real time. Email notifications are triggered by low or expiring quantities. Establishing an off-site, high-density storage facility was dependent on having an accurate inventory system, obtaining space from NYULH Real Estate Development and Facilities (RED+F), establishing workflows for transporting supplies to the laboratory, and investment in laboratory research assistants (LRAs) aimed to support this expansion. In 2020, PCC worked with RED+F to obtain 11 Metro qwikTRAK high-density units for 3,300 sf of new shelf space. A 1,300 sf off-site facility 8 city blocks from the RBMU laboratory was designed to house 2,400 sf of this shelf space.

4. Outcomes

In 2018, RBMU implemented the first LIMS LabVantage clinical trial kit inventory system. In 2020, RBMU hired 1 LRA to support off-site inventories and coordinate transport with courier services weekly. As of 2021, the median time from kit delivery to storage is 7 (range: 0-14) days and the median time from kit expiration to destruction is 20 (range: 1-30) days. The system made establishing an off-site storage facility feasible and enabled a 536 percent increase in storage space, from 550 sf of shelving to a total of 3,500 sf. An inventory system, in combination with high-density storage, proper staffing, and efficient workflows, mitigates delays in activating trials due to misplaced supplies and maintains accurate inventories for over 250 protocols – monitoring over 3,000 kits.

5. Lessons Learned and Future Directions

Comprehensive maintenance of supplies along with adequate storage space is crucial for the proper conduct of a large portfolio of trials at an institution. A functional inventory system is a valuable tool for efficient study management. Establishing a custom clinical trial management system facilitated a downstream project which included integration between Epic electronic medical record (EMR) and LIMS LabVantage to track patients' blood draw appointments.

Figure

Before

