

Piloting a “Just-in-Time” Model to Improve Efficiency and Accuracy in Phase I Clinical Trials Pharmacy Order Creation Process

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1. Background

Safe care delivery, accurate data collection and efficient order creation is essential to the success of clinical trials. Research protocols provide the guidelines necessary to implement the schedules of events and drug administration. It is up to the participating institution to translate those requirements into an effective pharmacy order(s) and a data collection document(s). Prior to 2014, the process of order creation was pharmacist and primary investigator (PI) driven. Often, order creation was delayed due to pharmacist workload, preventing timely study enrollment for potential patients. In January 2014, a systematic and multidisciplinary approach to creation and implementation of research orders was conceived in the form of the research order committee. Clinical trials infusion nurses collaborated with clinical research coordinators to create the tables that outline patient care tasks and data collection time points as specified in the research protocols.

In 2016, to further refine the order creation process and increase efficiency of document completion, the research pharmacy order was split into two working documents: pharmacy order and nursing considerations. This substantially improved formatting and provided additional space for pertinent nursing care guidelines. With the new process in place, the time from Scientific Review Committee approval and committee notification to first draft creation decreased by 18 days (54%) and total time required for order completion and approval decreased by 52 days (55%) in 2017.

2. Goals

However, as committee participation increased and workflow efficiency improved, a new challenge emerged. The backlog of orders that had once existed was eliminated but protocol assignments were now completed months in advance of SIVs study opening and patient enrollments to treatment (averaging 7.6 months). Often multiple amendments and/or changes to phases or cohorts would go into effect prior to document utilization, requiring multiple edits before patient enrollment. This increased the challenges faced with phase I studies, that often require documents for multiple cohort and as a result several unnecessary documents are often created and never utilized.

3. Solutions and Methods

Due to these challenges, a “just-in-time” model was proposed as the new work flow model for research order creation. The collaborative team, plans to adjust the deadlines for pharmacy order creation to be completed two weeks from the SIV. The goal is pharmacy orders will be completed in this time frame with nursing considerations completed once a patient has been identified. The intention of this timeline is to ensure that the most accurate documents are created from the most current protocol versions and sponsor information. The goal being to reduce the number of order sets that need revision while reducing the need for repetitive review/approval by the PI.

4. Outcomes

Category: Clinical Trials Operations - Completed Project

The Phase I team at Winship Cancer Institute of Emory University is currently piloting the “Just-in-time” model for several of our multi-cohort studies. We began this process by first focusing on two of our programs’ more complex trials. These trials include multiple cohorts with various dosing schedules.

5. Lessons Learned

This process is allowing us to test out our efficiency and accuracy as we move to generate orders with potential patient identification as the trigger.