

Clinical Research: Following the Money Phase III

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1. Background

Prior to the development of the clinical research accounting system (RAS) at UAMS, there was no consistent or efficient method to track incurred clinical trial revenue or expenses. Although in-depth budgets were developed for each clinical trial, there lacked streamlined accounting processes across all clinical research departments for tracking revenue or expenses when they were incurred. We required a system that could efficiently track earned invoiceable, milestone, and start-up revenue while accounting for incurred expenses to allow for appropriate reconciliation of clinical trial accounts. Also needed was an efficient method of comparing earned versus received revenue and incurred versus paid expenses. Lastly, we had no way to answer campus leadership financial questions without tedious, manual collation of data from multiple systems including the UAMS enterprise finance system (SAP), clinical trial management system (CTMS) and electronic medical record system (EMR).

2. Goals

Our goal was to create streamlined processes for efficiently tracking billable items through robust integration with our CTMS managing receipt of payments, facilitating fund transfers between departments, and reporting clinical trial revenue and expenses on an accrual basis. This function creates a simple notification when a study incurs an expense or earns revenue allowing our financial analysts to create invoices in a timely manner.

Metrics used to evaluate milestones were:

- Revenue from invoiced procedures
- Revenue from milestone procedures
- Revenue from start-up processes
- Institutional expenses posted to the clinical trials
- Unfunded procedures

Based on these five metrics, reports can be generated by a number of criteria.

3. Solutions and Methods

Our information technology research systems team, through in-depth collaboration with multiple research and finance teams, developed the RAS to capture financial activity associated with clinical trials. RAS imports information from our CTMS to provide both study and subject-level clinical trial procedures at the contractual rate for a clinical trial. RAS generates customizable invoices, which can be sent to the sponsor for payment and, through integration with SAP, allows us to track receipt of payment. Incorporation of reporting capabilities allows accurate tracking of clinical trial accounting methods to preserve financial profitability.

4. Outcomes

Since the inception of this program, we have been able to successfully track, report, and post revenue and expenses for our clinical trials in an electronic program. Comprehensive integration with SAP and the CTMS reduced routine and often duplicative manual processes. We are now financially managing

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220 oncology clinical trial accounts (industry, cooperative, and investigator-initiated) and have been able to adequately track revenue and report expenses related to clinical trials. This has allowed us to report more accurate figures to campus leadership in a timelier manner.

5. Lessons Learned and Future Directions

Phase III of this project is underway. It brings additional reporting abilities including an income statement that can be run per study, per disease type, per study type, or for all studies with activity in the chosen time range, which will be integral in our communication with campus financial leadership. Enhancements are ongoing and additional features will be implemented as we progress forward.