

The Significance of Financial Audits in Sustaining Clinical Trial Operations Amidst Shifting Industry Trends

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1. Background

Similar to other academic medical institutions, we experienced significant turnover in recent years, with coordination and finance staff enduring a 59 and 42 percent turnover rate, respectively, since July of 2021. Seasoned staff departed and existing team members were tasked with additional responsibilities as the complexity and volume of trials increased. Our team omitted inputting data necessary to properly invoice sponsors during this period. Additionally, we began the rollout of OnCore Financials and the implementation of Coverage Analyses. We entrusted our staff with learning these novel systems while maintaining our financial legacy system in Excel.

2. Goals

Facing declining revenues and falling accruals due to industry shifts toward stricter enrollment criteria, our team was assigned the responsibility to conduct a comprehensive review of our financial model with the objective of identifying process enhancements to mitigate our fiscal challenges. There existed an opportunity to improve our overall billing model, budget strategy, accuracy, and timeliness of charge segregation, and subsequently properly invoice for those items. With hiring limitations, our team was tasked with implementing these efforts in our existing workload.

3. Solutions and Methods

We defined an audit scope and evaluated internal controls with an experienced team. Epic's SlicerDicer was a new tool introduced with a multitude of uses for displaying clinical and financial data, with seamless accessibility and visualization capabilities. SlicerDicer pulls a list of all procedures and associated charge codes across studies. This information is placed into an Excel model developed by our team and thoroughly cross-referenced to the study budget and items previously billed to the sponsor. We bill unbilled items accordingly after verifying with coordination staff. A reporting and communication strategy was developed to educate staff and improve training.

4. Outcomes

The audit program has been a resounding success, recovering \$1.1 million in previously unbilled items in three months. In the early phases, our primary focus is on trials that are struggling financially and trials that are closing. Other benefits of the audit program include:

- Improved billing compliance, ensuring we are not erroneously billing sponsors for procedures that were directed to insurance
- An evaluation model for our activation and maintenance teams, confirming accurate budgeting and revenue collection for our studies
- Identifying new budgeting opportunities
- Increased accuracy in data reported to sponsors from clinical coordination as the dates of tests and procedures are meticulously reviewed

5. Lessons Learned and Future Directions

Our outdated Excel system was lacking in many areas and a rethinking of our processes was necessary to keep pace with the volume and complexity of trials. Ensuring we are properly billing and budgeting for

all relevant procedures is the backbone to sustain a fundamentally sound operational budget and maintain opening trials tailored to our patient population. Future goals involve:

- Improving internal controls to reduce workflow redundancies with our coordination staff
- Enhanced billing compliance
- Continued revenue recovery
- Verifying OnCore Financials are set up and maintained accurately

We will perform real-time audits to lessen review work for closing trials. OnCore will eventually mitigate a majority of our audit findings, but we are a few years away from being fully integrated in the system.

Figure

