

Holden Comprehensive Cancer Center

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

Alec Shultz, CPA, Jessica Gallagher, MBA, Sayed Al-Tabar, Alyssa Pratt, MS, CCRP

Background

- Since July of 2021, we have experienced 59% turnover in coordination staff and 42% in finance.
- Increased workload and trial complexity, despite reduced and inexperienced staff.
- Key data points necessary to invoice sponsors were missed during this period.
- Implementation of OnCore Financials and Medicare Coverage Analyses, with staff training on these new workflows while managing legacy financial systems in Excel.
- Decreased revenues and enrollments due to industry's stricter enrollment criteria.

Goals

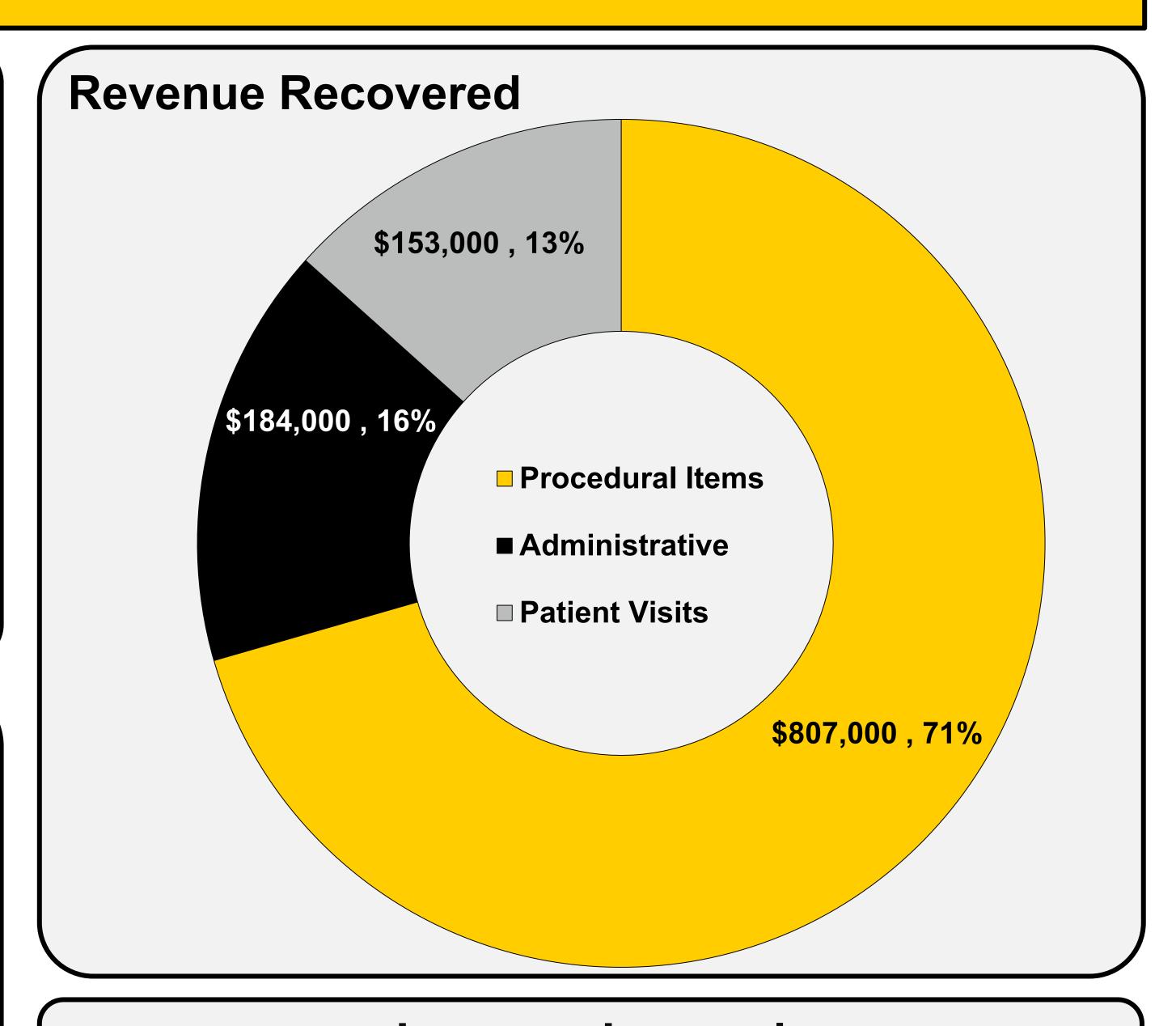
- Conduct a comprehensive review of our financial model with objective of identifying process enhancements and mitigating fiscal challenges
- Opportunity identified to improve:
 - Overall billing model
 - Pre-award budgeting strategy
 - Accuracy and timeliness of charge segregation
- Tasked with integrating improvements into current workload despite hiring limitations.

Solutions and Methods

- Defined an audit scope and developed an overall strategy.
- Evaluated internal controls.
- Utilized EPIC's SlicerDicer for visualizing financial data and extracted list of procedures and associated charge codes across studies.
- Data integrated into a custom Excel model, cross-referenced with study budgets and past billings.
- Ensured accurate invoicing of unbilled items after verifying with coordination staff.

Outcomes

- Audit program recovered \$1.1 million in unbilled items within three months
- Focused on financially struggling and closing trials in early phases.
- Improved billing compliance and new riskassessment tool.
- Evaluation model for activation and maintenance teams to ensure accurate budgeting and revenue collection.
- Identified new budgeting opportunities to combat industry trends.
- Increased accuracy in data reported to sponsors due to meticulous review of procedures and associated dates.



Lessons Learned

- Recognized need to update our Excel system due to increased trial volume and complexity.
- Proper billing of procedures is crucial for maintaining operational budget and team efficiency.
- Plan to perform real-time audits to reduce burden required for closing studies.
- OnCore expected to significantly reduce audit findings, with full integration of legacy studies projected in a few years.

