Amendments Post-Activation

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Background

- Moffitt Cancer Center Clinical Trials Office (CTO) has 12 disease and 7 therapeutical departments. These departments support phase I-III interventional therapeutic clinical trials across all oncology disease sites.
- Moffitt CTO exponential growth, increasing complexity in the requirements in oncology clinical trials, combined with the increasing number of clinical trials protocol amendments, CTO and other shared resource departments were experiencing backlog of amendments.
- CTO partnered with our Clinical Research Revenue Cycle department to develop ways to track total number of protocol amendments and share this data with senior leadership.

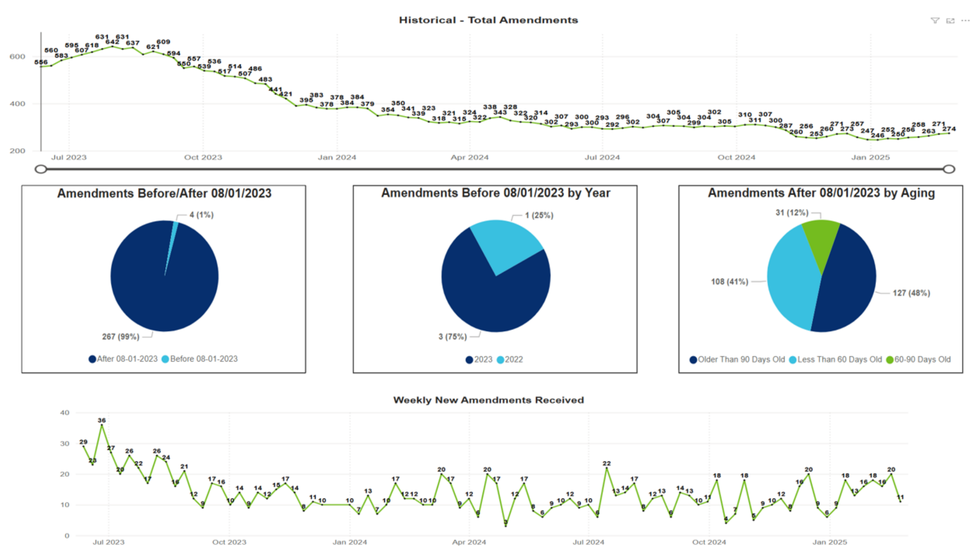
Goals

- Standardize process for amendments received post-activation and determine service level agreements (SLAs).
- Design a dashboard that could be utilized by cross-functional operational leaders to provide visibility on amendment backlog cleanup and track protocol amendments quantity.
- Create a dedicated team for reviewing amendments and identifying impact on all operational areas.

Solutions and Methods

- Whiteboarding sessions were conducted to discuss and outline our standard for processing amendments post-activation.
- Amendment Task Force team was created to develop amendments post-activation standard operating procedures document and detailed workflows.
- Education and training of all operational areas on new standardized process.
- Development of Amendment Dashboard allowing visualization of the metrics, historical data, and overall timeliness of implementing amendments.
- Established Amendments Post-Activation dedicated team and created new Clinical Trails Amendment Coordinator role.

Outcomes



Outcomes ?? Metrics/Improvements?

- Total number of amendments decreased by 80% since July 2022.
- Number of Amendments with financial implications decreased by 64% since July 2022.
- Monitoring newly closed to accrual studies to re-access impact and use of shared resource departments.
- Review of amendment impact standardized – 5 days for NCI and Cooperative Group trials and 14 calendar days for Industry funded and Investigator Initiated Trials.
- Proactive planning of amendment implementation based on its impact with focus on compliance and accurate billing.

Refinements and Next Steps

- Incorporate SLA tracking to Amendment Dashboard to help with monitoring of different steps and timely implementation.
- Keep evaluating and refining each step of the process to meet our implementation goals.
- Keep evaluating CTO capacity and need for additional resources based on amendment metrics and data changes over time.
- Explore solutions for quicker implementation of early therapeutics/Phase 1 trials.