Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

Amendments Post-Activation

N. Ugrenovic, M. Davis, J. Lebsack

Moffitt Cancer Center

1. Background

Moffitt Cancer Center's continued growth (~6%YOY) combined with increasing complexity in the requirements in oncology clinical trials, and operational challenges contributed to backlog of amendments. CTO partnered with our Clinical Research Revenue Cycle department to develop ways to track total number of protocol amendments with senior leadership.

2. 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.
- Reduce the number of amendments and days an amendment is in the process.

3. 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.

4. Outcomes

- Total number of amendments decreased by 80 percent since July 2022.
- Number of Amendments with financial implications decreased by 64 percent 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.

5. Lessons Learned and Future Directions

- 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.

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

- 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.

Figure