

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

Streamlining Amendment Process Through Development of a Standardized Process and Centralized Amendment Support Team

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1. Background

Historically at Moffitt Cancer Center (MCC), processes for managing protocol amendments within the Clinical Trials Office (CTO) existed informally and lacked standard operating procedures, workflows, and a dedicated role to manage amendment review. Over time, responsibilities were distributed across multiple positions resulting in variable practices and inconsistent oversight. As MCC expanded and the volume of active studies and amendment submissions increased, operational inefficiencies became more evident. Delays in receiving updated materials from sponsors and CROs contributed to inconsistent amendment timelines. These challenges highlighted the need for a more standardized, centralized, and scalable process to support effective amendment management.

2. Goals

- Establish dedicated team as primary point of contact for all amendment-related questions.
- Improve the speed and consistency of amendment processing by implementing standardized workflows that support timely amendment review and submission to regulatory committees.
- Support MCC's growing clinical trial portfolio by implementing a scalable amendment management process that ensures consistent turnaround times, timely regulatory submissions, and prompt collection of required study materials.

3. Solutions and Methods

- Established a centralized amendment-processing team by developing and approving the Clinical Trials Amendment Coordinator (CTAC) job description through appropriate departments.
- Analyze historical and current amendments volumes to ensure appropriate resourcing and determine the number of full-time equivalents (FTEs) required to support operational needs.
- Developed targeted training and onboarding for CTACs combining components of the Human Subject Research Academy curriculum alongside role-specific modules created by the CTAM to address amendment-focused workflows.
- Implemented the CTAC workflow with the team beginning formal amendment review and processing in August 2023, including collection of required study documents and updated materials.

4. Outcomes

Amendment Review Timelines:

- Number of amendments received in 2021 – 385 days, average time for reviewing 20 days (shortest zero vs longest 445).
- Number of amendments received in 2022 – 338 days, average time for reviewing 26 days (shortest zero vs longest 684)

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- Number of amendments received in 2023 – 416 days, average time for reviewing eight days (shortest zero vs longest 97, this is still prior to CTAC role, after CTAC role longest is 19 days)
- Number of amendments received in 2024 – 448 days, average time for reviewing four days (shortest zero vs longest 17)
- Number of amendments received in 2025 – 678, average time for reviewing four days (shortest zero vs longest 45)

SLAs for Amendment Review Constant Despite Increased Amendment Volume

- The percentage increase in number of amendments received from 2023 to 2024 was 7 percent and from 2024 to 2025 was 51 percent.
- Since August 2023, amendments have been reviewed within SLAs 97 percent of the time with a median of two days.

5. Lessons Learned and Future Directions

- Continue evaluating staffing needs through ongoing effort/workload tracking to ensure sufficient resources for CTO amendment activity as MCC grows, while maintaining SLAs.
- Expand CTAC responsibilities to standardize additional high-burden tasks—such as amendment implementation follow-up with shared resources—to further streamline operations.
- Assess the optimal team structure, including whether high-complexity areas (e.g., Early Therapeutics/Phase I) require a dedicated CTAC or if a shared model remains most effective.