

# Amendments Centralized Team

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## 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.

## Goals

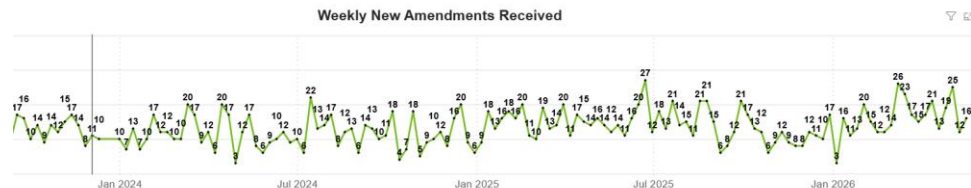
- Establish dedicated team as primary point of contact for all amendment-related questions.
- Improve the speed and consistency of amendment processing by implementing standardized workflows that support timely amendment review and submission to regulatory committees.
- Support MCC's growing clinical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

## 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) needed 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.

## Outcomes

Year	# of amendments received	Avg. review time	Shortest	Longest
2021	385	20	0	445
2022	338	26	0	684
2023	416	8	0	19
2024	448	4	0	17
2025	678	4	0	45



## Outcomes

- SLAs for Amendment Review significantly lower with centralized amendment team support compared to years prior to team establishment
- The percentage increase in number of amendments received from 2023 to 2024 was 7% and from 2024 to 2025 was 51%. Despite increased amendment volume SLAs remain lower than years prior.
- Since August 2023, amendments have been reviewed within SLAs 97% of the time with a median of 2 days.

## Lessons Learned and Future Direction

- Continue evaluating staffing needs through ongoing effort/workload tracking to ensure sufficient resources for CTO amendment activity as MCC grows, while staying within agreed 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.