Creating A Specialized Regulatory Office

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Background

In 2021, the need for specialized regulatory management and personnel was identified by the University of Arizona Cancer Center (UACC) Leadership. To increase productivity and remove inefficiencies, a gradual implementation process to specialize the regulatory office began, initiated by splitting the staff according to trial type and incorporating start-up-focused roles and active-trial-focused roles.

Goals

The goal of specializing the regulatory office is to advance trials through the activation process faster and ensure regulatory compliance for active trials is maintained to the highest standards.

Solutions and Methods

UACC Leadership was critical in first identifying the need to specialize the regulatory office. The rollout of this plan occurred in several phases, starting in 2021.

PHASE 1 [November 2021]: UACC Leadership implemented the first split in the regulatory office by creating a Trial Activation Manager position and two Investigator-Initiated-Trial Manager positions, who all work in tandem with the Regulatory Manager.

PHASE 2 [June 2022]: UACC Leadership & Regulatory Management (Trial Activation Manager and Regulatory Manager) then began implementing staff transitions, with the end goal being that each Clinical Research Team (CRT) has a start-up-focused coordinator and an active-trial-focused coordinator. The first CRTs that transitioned to this model were the Phase 1 CRT and GI CRT. It was critical to determine the strengths and weaknesses of each regulatory personnel to identify which CRT assignment would be the most effective. Key attributes sought after for start-up focused personnel are high levels of organization and responsiveness. The ideal qualities identified for personnel focused on active trials included those with a strong commitment to compliance and meticulous attention to detail. After building the foundation for this change, procedures to ensure that trials are transitioned between personnel upon activation were created and implemented.

PHASE 3 [January 2023-Present]: UACC Leadership & Regulatory Management (Trial Activation Manager and Regulatory Manager) then began to roll out the next phase after the successes experienced with the Phase 1 CRT and GI CRT. The Breast, Melanoma, Head & Neck, Lung, and Lymphoma CRTs were all transitioned per the model used for the Phase 1 and GI CRTs.

Outcomes

After the specialization of the regulatory office was completed, many benefits were realized. Staff training became more focused and specific, resulting in staff being operational and independent in a shorter timeframe. The staff focused entirely on start-up were able to identify inefficiencies and resolve matters of significance at a faster pace than what had occurred in the past, helping decrease timelines on tasks and procedures under our control. The staff focused on maintaining active trials were able to address action-items on monitoring reports faster to keep queries to a minimum, process and distribute IRB-approved documents immediately upon receipt, and devote adequate time to ensuring deviations and SAEs were being processed and submitted to the appropriate regulatory authorities. Additionally, as the CRTs became more familiar with each other, relationships between investigators and site staff grew, creating more positive impacts to our Cancer Center.

Lessons Learned and Future Directions

The specialization process at UACC has successfully increased efficiency in training and has also helped grow the relationships between regulatory personnel and their physicians. The staff have subsequently been able to focus on their specialty, resulting in a smoother activation process for our new trials and ensures all active trials are audit-ready at all times. There are several clinical research teams that remain to be adjusted, which will be the next set of obstacles to overcome.

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