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

Implementing a Non-Therapeutic Activation Team at a Comprehensive Cancer Center

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1. Background

At Moffitt Cancer Center, the Non-Therapeutic Research Office (NTRO) was created in 2021 to provide centralized support for our non-therapeutic research (NTR) portfolio of ~700 studies. Within this novel structure, a new manager-level position with focus on study activation and research support was created. Prior to this, NTR study activation needs were managed in siloed departments which often created confusion, inconsistency of process, and contributed to delays in activation. The team that we developed within NTRO is staffed with a manager, activation coordinators, a data analyst, and a staff scientist who provide comprehensive logistics and planning, budgeting guidance, and NTR expertise to faculty customers navigating the activation process.

2. Goals

The goal for creating an NTR-dedicated study activation team was to provide expertise and concierge-like service to specifically address the unique needs of NTR research and to provide holistic advocacy throughout the study lifecycle. With the dedicated focus of a NTRO operational manager over this area, we sought to create efficiencies and robust, consistent processes to support our NTR portfolio by also reducing some of the administrative burden to faculty/study teams and our operational stakeholder departments involved in study activation.

3. Solutions and Methods

The NTRO study activation team is required to have broad expertise in all aspects of NTR research, including the following implementation requirements: 1) various funding structures (e.g., grant- vs. industry-funded), 2) NTR interventional vs. observational research, 3) population, community-based, and translational research methodologies, 4) appropriate utilization of Moffitt's biorepository infrastructure and other Shared Resources, and 5) regulatory and compliance implications across the spectrum of study-related needs. We also partnered with our Clinical Trials Office (CTO) to develop a decision tree to define which group (NTRO vs. CTO) will manage a given NTR study. This pragmatic tool allows for aligning the team with the best expertise to successfully and compliantly manage a study. For example, if a NTR study has an IND/IDE or any FDA-regulated components, the study would be aligned to CTO for management. Lastly, to generate awareness about our service, we presented to numerous clinical and academic programs about the NTRO study activation team and services available.

4. Outcomes

We expanded our partnerships with internal stakeholder groups across all aspects of NTR study implementation. This includes, but is not limited to, the Clinical Trials Business Office (negotiates budgets and contracts), Shared Resources, Regulatory, and Compliance towards the goal of increasing overall compliance while also striving to decrease activation times.

5. Lessons Learned and Future Directions

Intentional and consistent partnership with our faculty customers and internal stakeholder departments is at the forefront of successful study activation. Non-therapeutic research at Moffitt Cancer Center is brimming with novel and innovative methodologies, often just as complex as treatment trials, and requires deep knowledge of the NTR landscape to appropriately manage and facilitate the distinct needs

of this portfolio. As we continue to grow, we will further develop and improve our workflows and monitor key metrics to ensure the NTRO study activation team is appropriately staffed. We will also pursue new training/educational opportunities to improve our knowledge and services.