Category: Trial Start-up, Activation, and Protocol Development – Completed Project

Harmonious Activation of Oncology Protocols Across an Integrated Academic Health System

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1. Background

In January 2019, Rutgers University (RU) and the RWJBarnabas Health (RWJBH) system entered into an agreement to form an academic health system (AHS). As a result, we had an extraordinary opportunity to expand Rutgers Cancer Institute of New Jersey (CINJ) clinical research to nine of the 14 hospitals of RWJBH. In this newly integrated, unified "one site" model, CINJ has unprecedented numbers of patients at its disposal for clinical research activities to positively impact our catchment areas priorities and needs.

2. Goals

To promote and simplify access and implementation of clinical trials to increase accrual and engagement at CINJ and RWJBH sites

3. Solutions and Methods

The Office of Protocol Activation (four FTEs) was established in December 2021 to streamline, standardize, and support feasibility and clinical trial activation activities across the organization. Our process beyond the regulatory, budget, and contracting start-up activities focuses on engaging investigators at our system sites and their research staff. Upon SRB approval, the office sends a study interest form (SIF) to all health system sites. Interested investigators complete the form with the number of anticipated enrollments and then each of these interested RWJBH sites is added to a single IRB application. The team tracks other activation tasks such as Epic Beason order set drafts, investigational drug and labs kit availability, and documentation of IRB approval. Once the trial is IRB approved, the office schedules one SIV, which is now conducted remotely and universally. Attendance and training are documented in the electronic regulatory binder (eREG®).

4. Outcomes

The Office of Protocol Activation has had substantial impact in CY2022.

- Reduced time from SRB submission to trial activation from 167 to 72 days (↑232 percent)
- Model allows OHRS the ability to open trials simultaneously at up to eleven clinical sites with a single IRB approval and systemwide SIV process
- Reduced open to accrual to first subject enrolled from 45 to 41 days (↑9 percent)
- Ninety-four unique investigators enrolled 600 subjects to interventional treatment trials in CY2022; overall accrual increased 33 percent (n=423) with a significant 300 percent increase in RWJBH system enrollments from CY2021
- Interventional treatment accruals to underrepresented populations within our catchment area has increased from 38.3 percent to 45 percent in CY2022

5. Lessons Learned and Future Directions

Educating sponsors on the value and strength of our system took a significant investment in time up front but facilitated our ability to open trials at multiple locations. Centralizing protocol activation activities allowed streamlined communication with sponsors, legal, finance, and regulatory, which was critical to getting studies activated quickly. Future directions include:

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- Continuing to enhance operational efficiencies in order to increase accrual and reduce time to activation to meet our goal of $\leq$ 60 days
- Utilizing Deep 6 AI and Epic to assist ensure catchment area needs and priorities are appropriately captured on feasibility assessments
- Focus on promoting more Phase III trials, particularly from NCTN, to meet the needs of the patients treated by a large number of primary oncology providers practicing across the RWJBH System; we continue to promote the “culture” of clinical research at all sites