Category: Training and Career Development – Completed Project

Investing in Investigator Training: Developing Tools to Close the Gap

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1. Background

Internal feedback from the University of North Carolina Lineberger Comprehensive Cancer Center (LCCC) investigators revealed an unmet need to provide readily available tools and training to educate investigators on the intricacies of developing, obtaining approval, and maintaining investigator-initiated trials (IITs), especially from those with no prior IIT experience. In fact, several investigators voiced concern and frustration during the development of their IITs when their own lack of understanding led to delays in the activation, a multitude of protocol amendments and/or noncompliance with investigational new drug (IND) regulations.

2. Goals

The goal of this initiative was to rebuild the University of North Carolina-LCCC IIT website to create a comprehensive training curriculum to minimize the gap in education between the onboarding of new investigators and the development of their IITs and to prevent noncompliance with FDA IND regulations.

3. Solutions and Methods

An initial lecture on IND management was developed in 2017 and LCCC investigators were invited to attend. An impressive 23 physicians attended despite their clinical schedules and duties, emphasizing the desire for IIT education. All were fully engaged in the discussion, leading the session to run over its allotted 1-hour timeframe as both junior and senior investigators asked questions and shared stories from their IIT experiences. This led to the development of yearly lectures on various IIT topics, with the 2021 lecture maintaining high attendance (34 investigators), and the re-development of the LCCC IIT website to function as a process warehouse where investigators can readily access training and education. Twenty-four webpages were developed to provide education on a variety of IIT topics including: how to identify funding and prepare a letter of intent, how to develop a clinical protocol, and to how work with drug/device regulations. Furthermore, a series of 15 IIT-focused beginner and advanced level lectures are housed on the website which provides a destination for asynchronous learning. Importantly, these trainings highlight the PI responsibilities for an LCCC-sponsored IIT.

4. Outcomes

The investigator-focused lectures and IIT website addressed the unmet need for investigator education. Significant IND noncompliance was identified at baseline, so one of our initial goals was to increase investigator understanding and compliance with IND regulations. In conjunction with other interventions, the implementation of training modules helped improve LCCC's IND overall compliance rating with the FDA regulations from 20 percent to 100 percent compliance despite an increase in IND portfolio complexity due to the addition of internally manufactured products. The informal feedback generated by this endeavor reaffirms that the incorporation of trainings and resources for IITs can significantly increase investigator understanding of the IIT process resulting in improvements in investigator communication, involvement, and compliance.

5. Lessons Learned and Future Directions

The endeavor taught us the importance of introducing investigators to training opportunities early and in a readily available platform to develop a strong foundational understanding of IITs. Our future

directions include the adaptation of the website to include guidance on non-treatment trials such as biospecimen, radiology, and health registry protocols, focusing on their unique needs.