Investing in Investigator Training: Developing Tools to Close the Gap

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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 and/or a multitude of protocol amendments associated with noncompliance with Investigational New Drug (IND) regulations.

Solutions and Methods

An initial lecture on IND management was developed in 2017 and LCCC investigators were invited to attend. Discussion from these sessions resulted in 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 the following: 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 Principal Investigator (PI) responsibilities for an LCCC sponsored IIT, **Figure 1**.

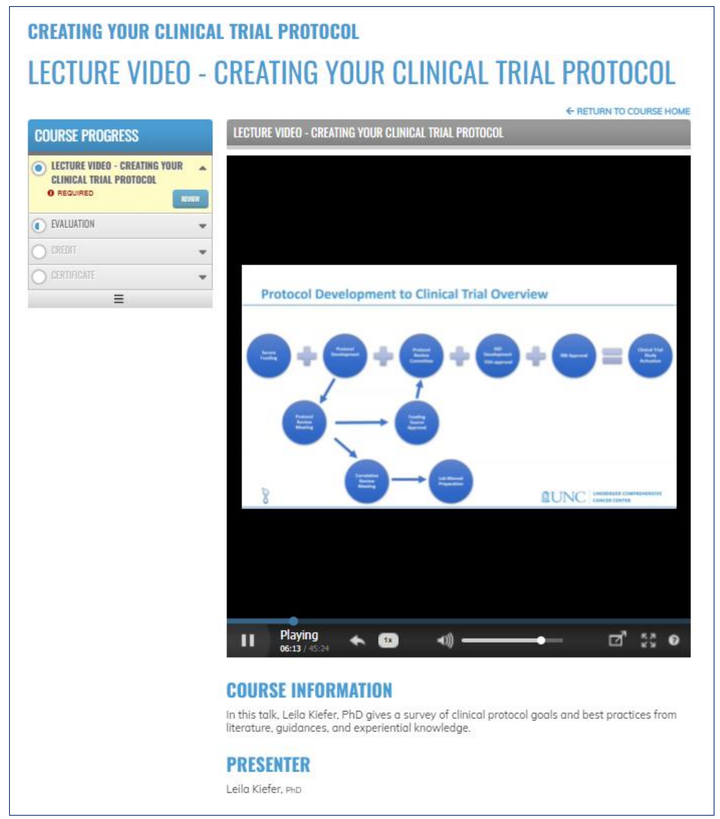

Figure 1: The goal of this initiative was to rebuild the IIT website to create a comprehensive training curriculum with asynchronous lectures that will minimize the gap in education that exists between the onboarding of new investigators and the development of their IITs.

Outcomes

The investigator-focused lectures and IIT website addressed the unmet need for investigator education. For example, noncompliance was noted as a major concern in IND management, and we identified significant noncompliance at baseline (**Figure 2A**). The lectures and website served as tool to increase investigator understanding and compliance with IND regulations. The initial lectures on IND management hosted an impressive 23 physicians in 2017 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 **Figure 2B**),

In conjunction with other interventions, the implementation of training modules helped improve LCCC's IND overall compliance rating with the FDA regulations from 20% to 100% compliance despite an increase in IND portfolio complexity due to the addition of internally manufactured products, **Figure 2A**. 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.

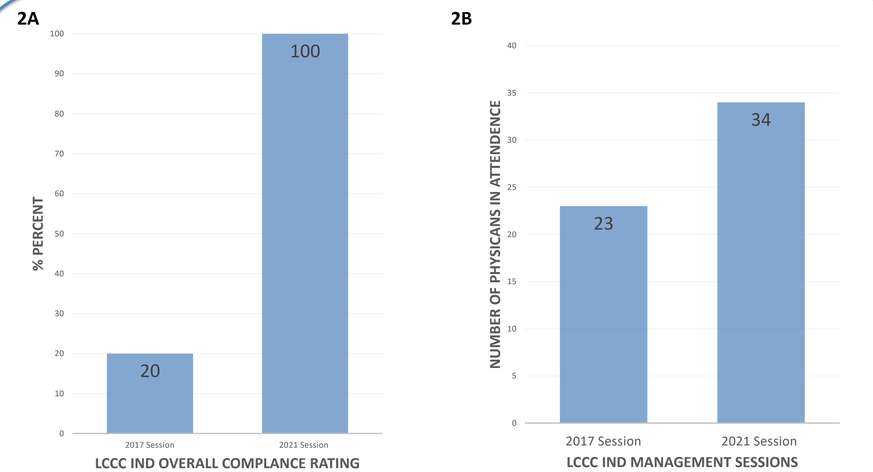

Figure 2: A: FDA compliance has increased from 20% to 100% as a result of the implementation of investigator training tools. B: Increase in demand of Investigator training sessions.

Conclusion

These results highlight the importance of introducing investigators to training opportunities early and in a readily available platform to develop a strong foundational understanding of IITs. 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.