Piloting a New Investigator E-Learning Onboarding Program

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1. Background
Principal investigator (PI) roles are complex. A formalized onboarding curriculum, created and delivered through the UFHCC clinical research office (CRO) and the research and training core (CaRTECC), was developed for new clinical investigators to provide knowledge and resources to help successfully conduct trials at UFHCC. This curriculum is anticipated to shorten learning curves for administrative and regulatory tasks, improve confidence leading trials, and ultimately decrease deviations. While generalized training exists providing broad coverage of PI competencies, this standardized onboarding will provide investigators instruction on specific research processes at UFHCC.

2. Goals
- Develop standardized clinical research onboarding curriculum for new investigators of varied backgrounds
- Increase new investigators confidence leading clinical trials
- Assess common knowledge gaps to create focused training modules to reduce errors impacting the institution via CAPAs or data deficiencies

3. Solutions and Methods
In January 2022, the UFHCC new clinical investigator eTraining (NCINET) was piloted with eleven new early-stage faculty. Of these, three completed the entire eight-module course and the remainder are expected to complete training in April. Following Knowles's core principles of andragogy, NCINET has immediate relevance to PI's role in clinical trials; each module is process-centered, using UFHCC policies as core texts. These documents outline clinical trial management, providing learning scenarios to highlight concepts including oversight, compliance, and consent. To maintain engagement and support motivation, learners can monitor individualized progress. By offering NCINET via a learning management system (LMS), investigators can access training and resources 24 hours a day. To ensure successful completion, investigators cannot be added to clinical trials as PI or Sub-I until the minimum passing score of 80 percent is achieved on all module assessments.

4. Outcomes
Five new investigators have initiated training, with three having completed the entire sequence. Initial data shows compliance and oversight domains had the greatest number of outliers (Figure 1). This suggests further module development may be needed, offering more situational practice. Individualized domain progress is also trackable.

The relationship between time spent on NCINET and mean scores across competencies shows a bimodal distribution, suggesting two cohorts working with curriculum (Figure 2). One group spent less time engaged with curriculum (<160 minutes) and the other group spent more time (>420 minutes). Both groups achieved mastery.

We predict more experienced investigators will achieve mastery in fewer hours of engagement than less experienced investigators. Further examination of metadata to link investigator experience with time spent in online training and competency mastery will be needed to study this hypothesis.

The relationship between page views (clicks) and mean scores across competencies was not statistically significant (p=0.29), suggesting number of views does not predict mastery, though the small sample size is a limitation (Figure 3).

5. Lessons Learned and Future Directions

Version 2.0 of NCINET curriculum will include a pre-/post-test, end-of-module surveys, and more interactive content. Assessments will undergo item analysis for outcomes alignment and to identify areas where more support is needed. Metadata will be collected to identify variables associated with investigator experience. A follow-up survey is planned to evaluate level of confidence in trial participation. Audit data will be examined to explore correlations between deviations and training.

Figures:

Figure 1: Competency Area Assessments

Figure 2: Relationship between time spent in online training and mean scores across competencies

Figure 3: Correlation between total clicks and mean scores across competencies