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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 (CaRTEC), 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.

GOALS

- Develop standardized clinical research onboarding curriculum for new investigators of varied backgrounds
- > Increase new investigator confidence conducting clinical trials at UFHCC
- > Assess common knowledge gaps to create focused training modules to reduce errors impacting the institution via CAPAs or data deficiencies

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Piloting a New Investigator E-Learning Onboarding Program

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METHODS

In January 2022, the UFHCC <u>new clinical investigator eTraining</u> was piloted with eleven new early-stage (NCINET) faculty. Following Knowles' core principles of andragogy, NCINET has immediate relevance to Pl'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. 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% is achieved on all module assessments.

RESULTS

Five investigators initiated training with three completing 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 igure 1: Competency Area Assessment

cohorts working with the curriculum [Figure 2]. One group spent less time engaged with the 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. Future examination of metadata to link investigator experience with time spent in online training ¹⁰⁰ and competency mastery will be needed to study this hypothesis.

The relationship between Figure 3 Correlation between total clicks and mean scores across page views (clicks) and competencies mean scores across Investigator: competencies was not statistically significant (p=.29), suggesting number of 85 views does not predict 80 mastery, though small 75 sample size is a 70 limitation [Figure 3] 65 Investigator Total Clicks

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.

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Relationship between time spent in online training and