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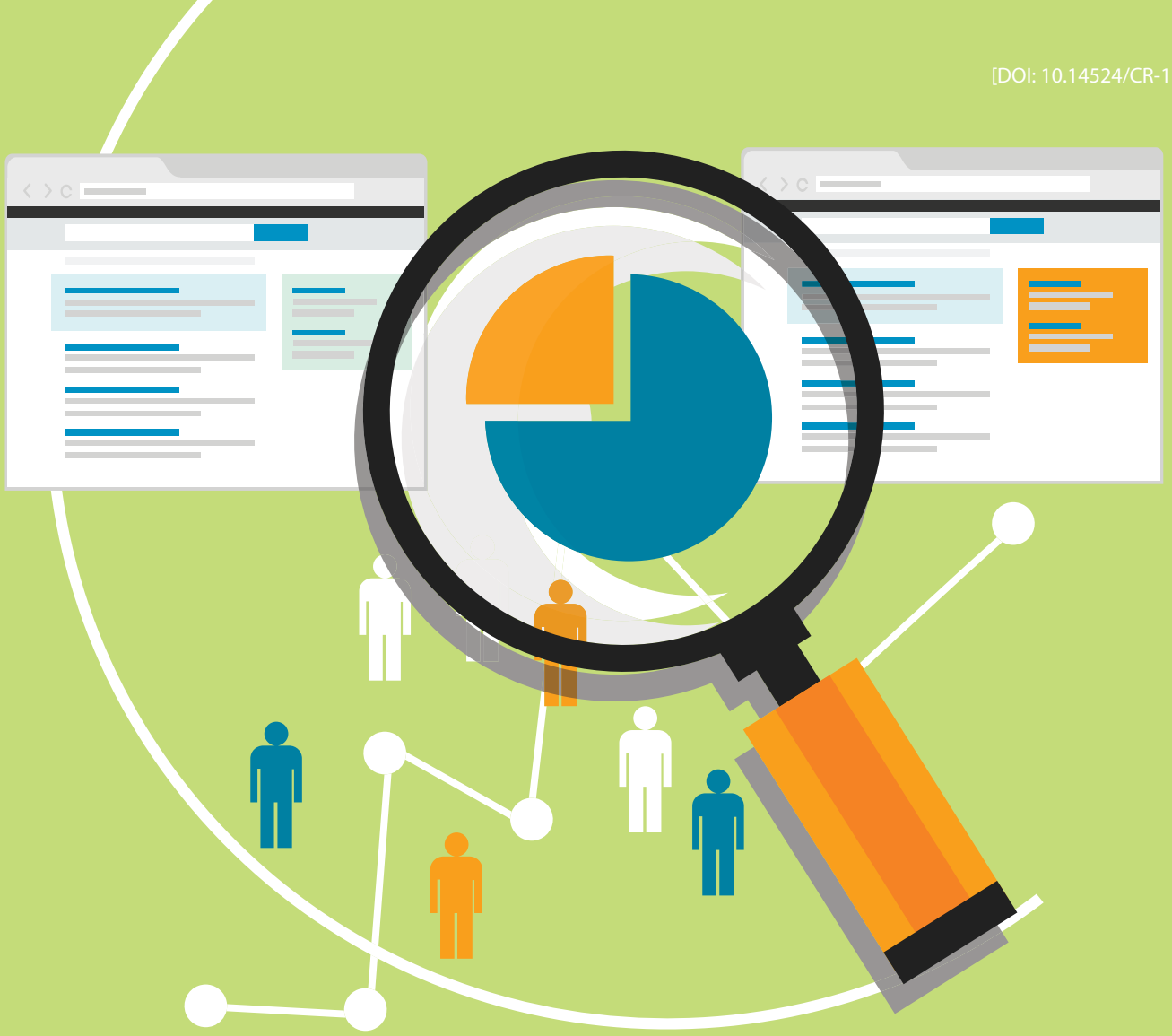

A Mixed Method Approach to Assessing Good Clinical Practice Computerized Online Learning

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Clinical research translation requires a trained, well-prepared workforce of clinical research professionals who can effectively conduct critical testing in clinical trials.[1] However, trials funded by industry and governmental sources have been criticized for inconsistencies in the design, execution, analysis, and reporting of clinical trial activity,[2] even as development of new drugs, devices, and behavioral interventions is one of the most highly regulated endeavors in the United States.[3]

Recently, the National Institutes of Health (NIH) mandated "all NIH-funded investigators and staff engaged in clinical trials research be trained in Good Clinical Practice (GCP)."

Management of clinical research at the site level is largely delegated to study coordinators who may manage multiple studies for principal investigators (PIs) with a high degree of autonomy. This takes place in an evolving interdisciplinary arena, where complexity is the rule rather than the exception. Importantly however, consistent requirements for providing and ensuring an appropriate level of qualifications do not exist.

A critical barrier to clinical trials is inconsistent—or even absent—competency-based training for all study personnel involved in clinical trials,[4] even as the Declaration of Helsinki opines, "medical research must be conducted by individuals with appropriate training and qualifications in clinical research."[5] While training and education of research staff is integral to the success of the team and the studies they work on, standardization of training is limited.[6]

Training for research staff often takes place within isolated academic departments, where there is variable quality in the content delivery. A competency tracking system to validate that staff have the knowledge and skills to meet data and safety standards may not be present. Further, inadequate training can lead to delayed startup, unmet enrollment goals, poor data integrity, and compromised research participant safety (e.g., during the consenting process), although clinical research professionals are held accountable for meeting these measures.

Background

Recently, the National Institutes of Health (NIH) mandated "all NIH-funded investigators and staff engaged in clinical trials research be trained in Good Clinical Practice (GCP),"[7] the tenets of which are promulgated by the International Council for Harmonization (ICH) and followed by researchers in such locations as the U.S., Canada, European Union, Japan, and Switzerland. Many programs, such as the Collaborative Institutional Training Initiative (CITI), which provides peer-reviewed, web-based educational courses in research, ethics, regulatory oversight, responsible conduct of research, research administration, and other topics pertinent to the interests of member organizations and individual learners, rely on standardized training systems; 60 of the 62 institutions supported by the NIH Clinical and Translational Science Award (CTSA) program currently use CITI training.

The nonprofit Association of Clinical Research Professionals (ACRP), meanwhile, which offers a variety of training, networking, and self-directed resources to its members and other stakeholders in the research community, has an on-demand eLearning platform designed to equip learners with the core concepts of GCP, among other topics.[8] Approximately 30% of CTSA institutions also utilize ACRP training.

CITI and ACRP platforms introduce users to the clinical research environment and regulations. Whether or not the process of obtaining competences is better achieved through online learning or structured work experience and mentoring has not been shown.[8] The purpose of the research described here was to assess the quality of online training in the ACRP and CITI learning platforms.

A randomized, mixed-method, quantitative-qualitative, sequential, explanatory design framed this study. Analysis of focus group data was used to corroborate, refute, or explain the results of the survey.

Participants and Their Preferences

Participants (interviewees) included volunteers involved in human subject research at any level at a large, public university in the southeastern U.S. that is part of the aforementioned CTSA program, without differentiation for gender and race. After institutional review board (IRB) approval, participants were recruited by placing posters on campus and sending e-mails to various mailing lists used by the research community. A total of 128 participants were needed to provide sufficient power analysis for this study.

Consenting participants accessed a CITI-developed online presentation on "GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)" and an ACRP-developed online presentation on "Good Clinical Practice: An Introduction to ICH GCP." Each participant was paid $100 for completing the training modules and the pre- and post-training surveys for both modules.

After first completing the randomly selected training module and survey, participants then completed the alternate training platform and survey a minimum of one week later. The Wilcoxon signed-ranks test was used to test for differences between the paired observations. Participants' responses determined their preference for one of the learning platforms on student learning

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variables including: (a) engaging, (b) ease of navigation, (c) satisfaction with scenarios, (d) content relevance, organization, and feedback, (e) hours to complete the online learning courses, (f) number of attempts to pass the module, (g) number of years engaged in research, and (h) type of responsibility. Level of significance in testing was set at $p \leq .05$.

Participants' preference for the ARCP training was statistically significant on the variables of engaging ($p \leq 0.0003$), ease of navigation ($p \leq 0.0205$), and hours to complete the course ($p \leq 0.0006$) (see Table 1). Compared to the mean of 2.3 hours for the ACRP training, it took participants a mean of 3.26 hours to complete the CITI course. Participants reported a preference for content organization and the opportunity for feedback in ACRP. Those with a preference for CITI were slightly more satisfied with the relevance of the content and expended less time in passing this course.

Focus Group Analysis

Further, 10 individuals were randomly invited from a pool of 132 participants for a focus group discussion, with nine individuals eventually participating and being compensated an additional $100. Participants' demographic information and responses to 22 survey questions were recorded in, and housed at, secure servers. Participants were asked to: (a) indicate time taken to complete the training modules, (b) preferred presentation style/method, (c) satisfaction with the material presented, and (d) satisfaction with the learning objectives.

TABLE 1: ACRP vs. CITI Learning Platforms on Student Learning Variables

Variable	ACRP Mean (Standard Deviation)	CITI Mean (Standard Deviation)	Wilcoxon Two-Sample Test p-value (Two-Sided)
Engaging	2.23 (0.84)	1.69 (0.97)	0.0003
Easy to Navigate	3.38 (0.92)	3.2 (0.65)	0.0205
Satisfaction with Scenarios	2.33 (0.54)	2.25 (0.54)	0.4265
Satisfaction with Relevance	2.41 (0.62)	2.43 (0.55)	0.9937
Satisfaction with Content	2.38 (0.58)	2.23 (0.57)	0.1338
Satisfaction with Feedback	2.21 (0.64)	2 (0.64)	0.0581
Hours to Complete	2.3 (1.25)	3.26 (1.71)	0.0006
Attempts to Pass Module	1.44 (0.62)	1.26 (0.44)	0.0961
Responsibility	1.98 (0.63)	2.1 (0.65)	0.3650

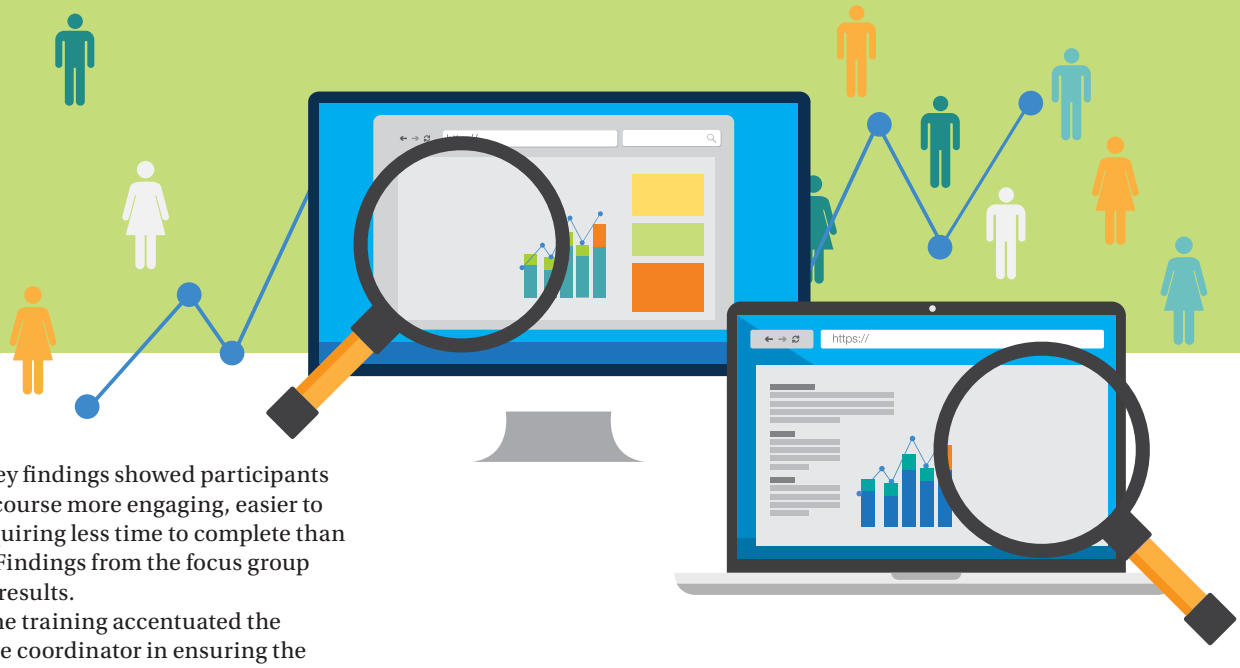
This single focus group was conducted to better understand participant experiences with the online learning platforms. Participants were all female; two African American and seven White. This methodology relies heavily on the skills of the moderator (interviewer) who: (1) introduces the topic in the same way, (2) ensures the conversation remains on track, (3) collects data related to the shared experiences among a group of participants, (4) develops an understanding regarding a phenomenon, and (5) encourages all participants to respond to questions (see Table 2).[9–12]

Three of the authors independently read the focus group transcript and formulated impressions of emergent themes. During a meeting, they reached consensus on the emergent themes and related conceptual definitions. Next, two authors selected two of the four themes and, while reading line by line, extracted selected text representative of the conceptual definition related to the theme.

These authors then audited each other's analysis to indicate agreement or disagreement with selected text. Use of the constant comparative method assisted in moving data to better fitting codes and codes to other categories or themes. This process resulted in some themes coalescing and others expanding; it involved coding, refining codes, identifying examples to support themes, making a master outline to illustrate relationships, and locating quotations to support the outline. The third author resolved any differences in opinion.

Four themes emerged, including: Self-Evaluation, Missing Components, Deviations, and Preferences (see Table 3). Self-evaluation refers to assessing personal skill level. Missing components refers to identifying content and topics not presented in the learning platforms. Deviations refers to pointing out protocol violations. Preferences refers to expressing predispositions for one of the two particular learning platforms.

Due to space limitations in the print edition of this journal, the research team's summary of the qualitative results from this portion of the overall research is shared as a supplemental document in the "Good Clinical Practice & Ethics" Interest Group hosted in the ACRP members-only Online Community (see https://www.acrpnet.org/networking/interest-groups/), and can be requested by non-members by contacting editor@acrpnet.org.



Discussion

Overall, the survey findings showed participants found the ACRP course more engaging, easier to navigate, and requiring less time to complete than the CITI course. Findings from the focus group confirmed those results.

Notably, online training accentuated the integral role of the coordinator in ensuring the quality and veracity of research, and enhanced participants' confidence levels. Also reported was how vastly different the training platforms were in terms of content relevance, organization, applicability, and assessments. Inability to have face-to-face interaction was an impediment to observation, and prevented opportunities for spontaneous peer-to-peer and peer-to-instructor interaction.

Other criticisms of the online learning platforms were that the questions and scenarios presented did not reflect the realities of day-to-day work. The findings supported the notion that the online learning platforms offered (a) no mechanism to validate staff attainment of knowledge or skills, (b) no evidence participants could consistently meet data and safety standards, and (c) no mechanism to ensure competency.

Overall, the findings highlight how obtaining competencies cannot be solely achieved through online learning. Further research is warranted, including replicating this design to see if the results are unique to our locale or if they will be similar at other CTSA institutions.

Coordinators felt vulnerable in a culture designed to protect institutions. Future research might be directed toward examining the inequalities and systems of power as they interlock with GCP regulations in a "relational, dynamic, processual, and mutually transforming character [as found] in any system of power differentials."[13]

Limitations

The researcher-constructed survey was not a validated scale. Without established psychometrics, the utility of the study findings must be considered in the context of these observations. Perhaps participants simply provided responses in terms of what they believed was essential, selected responses they thought researcher sought, or over-rated their skills. The study was carried out at single health science center, representative of only one of the 62 CTSA hubs.

TABLE 2: Focus Group Questions

1. Which platform, CITI or ACRP, best addressed your training needs?
2. Which section or module was the most important to you? Why?
3. Was there any element that was missing from either of these training modules that you feel would help you in carrying out your responsibilities as a coordinator?
4. How well did the CITI and ACRP platforms measure GCP competencies?
5. Can you recommend a platform for GCP training at the University of Florida: (a) CITI, (b) ACRP, (c) classroom, or (d) a combination? Explain why.
6. What essential skills or competencies for coordinator training and professionalization were not addressed in the GCP training program?
7. Has your confidence in your level of professionalization increased or decreased as a result of this GCP training program? Explain why.
8. How has GCP training program influenced your role as a research coordinator?
9. What aspects of the GCP training program influenced your own sense of being/becoming an ideal research coordinator?
10. As a result of the GCP training how confident are you in: (a) Identifying ethical and professional conflicts in conjunction with clinical trials and (b) Bringing observed ethical/professional conflicts within clinical trials to the attention of the PI or other designated authorities?
11. How often have you observed deviations in the last 12 months? (a) Did you bring this deviation to the PI's attention? (b) If so, did you discuss it verbally, via e-mail, or through both methods? How did the PI respond? (c) In other words, did the PI take your observation seriously and make the appropriate changes? (d) Did the PI simply acknowledge your concern, but not act on it? (e) Did the PI reject your observation of the deviation? (f) How would you handle a situation where you observe a serious deviation, but the PI does not take any action?

TABLE 3: Main Themes from Participants

Themes	Conceptual Definitions
Self-Evaluation	Assessing personal skill level
Missing Components	Identifying content and topics not presented in the learning platforms
Deviations	Pointing out protocol violations
Preferences	Expressing predispositions for particular learning platforms

Consenting participants accessed a CITI-developed online presentation on "GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)" and an ACRP-developed online presentation on "Good Clinical Practice: An Introduction to ICH GCP."

All nine individuals participated actively during the focus group; however, it is possible some may not have felt comfortable voicing their opinion or may have felt pressure to conform to the group's consensus opinion. Overall, the focus group findings are not generalizable. Also, the number of questions asked was restricted; the available response time for any participant to answer each question was necessarily limited in order to hear from everyone. Despite efforts made to systematize data collection through use of a standardized protocol, the potential for moderator influence cannot be determined.

The authors want readers to know that we have no potential conflict of interest with the products assessed in this study.

Conclusions

Although the CITI and ACRP platforms provide a solid introduction to the clinical research environment and regulations, they are not without advantages and disadvantages. Participants showed a clear preference for the ACRP platform, and the ACRP course took less time to complete compared to the CITI course.

The findings suggest that no single online training product adequately meets the guidelines set forth by ICH GCP or the intentions of NIH, in terms of developing a fully competent translational workforce. Future research should determine how competencies can be effectively and efficiently certified. Developing rubrics and criterion indicators and calibrating raters will likely be the next steps.

Acknowledgments

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