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Blind Spot in Clinical Trial Operations: *Who is Watching?*

PEER REVIEWED

Nadina Jose, MD | Roshan Padbidri, MS | Suzette Cody, MA

Who is watching when clinical trial stakeholders—the sponsors, contract research organizations (CROs), and sites involved—are spread out doing simultaneous business on multiple trials across the globe? Who is watching to make sure that every individual clinical trial project is proceeding through its milestones with every possible issue and risk properly identified and responded to?

The assumed answer is usually *everyone*—as in every stakeholder—and therein lies the problem. Everyone thinks everyone else is watching; however, the truth is, with everyone being overloaded with information, it is not humanly possible to track every issue in real time.

Mostly, issues are reported much later than is ideal, and with little or inadequate action taken.[1] Consequently, for example, one unattended query could become the basis for escalated data management discrepancies. Project delays and increases in projected study budget are more the norm than the exception. More important than the consequent increase in cost is the painful loss of timely access to treatment by waiting patients.
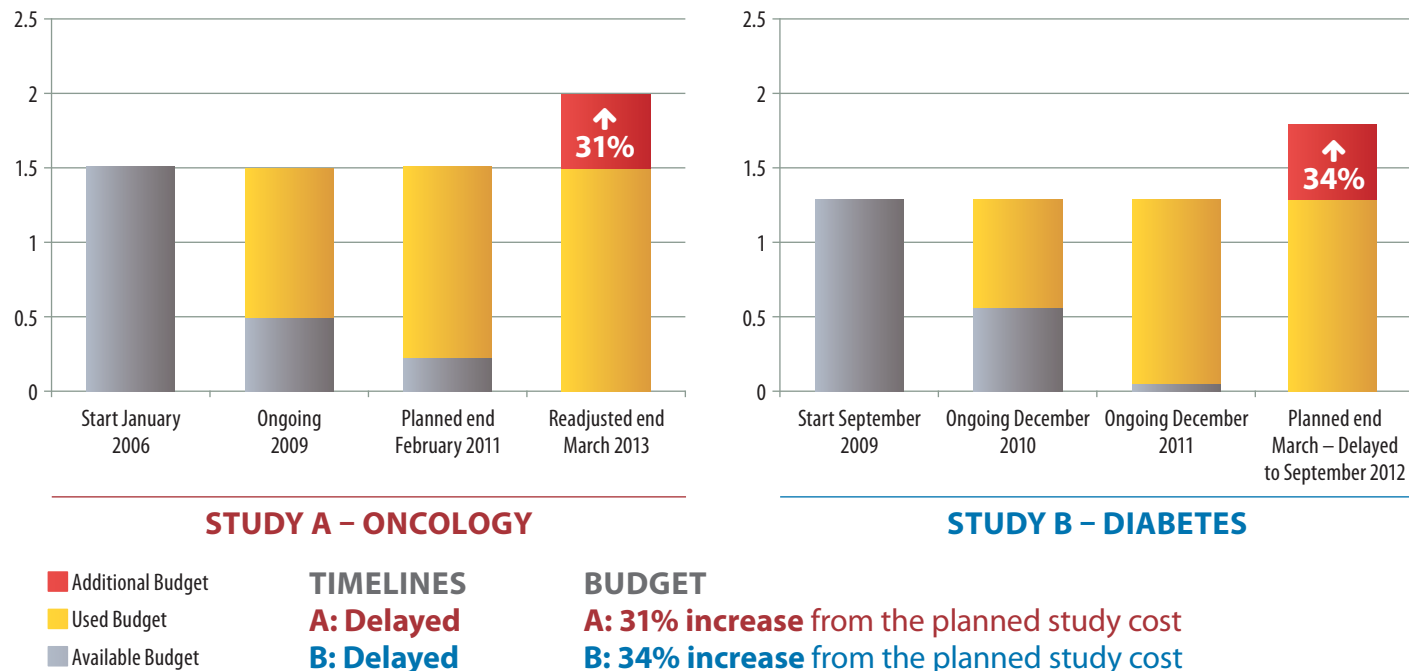
A Tale of Two Studies

Without disclosing either study's profile, we illustrate the philosophy behind "Who is Watching?" by describing the issues underlying delays in two studies. We reviewed the available data and results of interviews with the project team during the January–May period in 2012. Several unattended and unmitigated risks contributed to delays in completion and increased budgets for Study A (Oncology) and Study B (Diabetes) (see Figure 1). The issues listed below interrelate and impact each other, and many of them are broken out for examination in the sections to come:

1. Many unresolved queries[2] (Study A alone had nearly 10,000 total queries)
2. Insufficient monitoring caused by inadequate processes
3. Lack of staff training
4. Lack of documented communications among the stakeholders
5. Lack of structured handover
6. Insufficient vendor oversight
7. Insufficient contract oversight and tracking

DELAYS WITH SIGNIFICANT INCREASE IN COST, WHICH COULD HAVE BEEN AVOIDED…

STUDY A – ONCOLOGY

STUDY B – DIABETES

■ Additional Budget
■ Used Budget
■ Available Budget

TIMELINES
A: Delayed
B: Delayed

BUDGET
A: 31% increase from the planned study cost
B: 34% increase from the planned study cost

Unresolved Queries

About 40% of the queries for Study A were repetitive in nature, and about 30% were more than nine months old with no apparent documentation of reasons for the delay in being addressed. Multiple changes of project managers and local country operations teams were the immediate reasons for unresolved queries. Lack of query details in project management and communications documents with the data management vendor also helped to worsen the condition of outstanding queries.

For Studies A and B, contracts failed to adequately establish thresholds or specify how to manage the numbers and kinds of queries. Unresolved queries alone resulted in an increase in change orders that then increased the budget. Further, there were no interim face-to-face meetings or communication between the key clinical trial sites and the sponsor or monitoring staff. Reviewing the communication logs, particularly where minutes were kept, revealed that regular communications were nonexistent.

Insufficient Monitoring

Both studies lacked sufficient monitoring visits and well-defined processes. Although it is acceptable for long-term studies to have a reduced number of visits, it is essential to have processes to continue to monitor the quality of the data that the studies are generating. Since these were missing, several quality issues were overlooked, including monitoring of critical data points.

Monitoring data deficiencies were mainly due to limited onsite visits. Case report forms (CRFs) that were sent to data management did not undergo source data verification (SDV), resulting in repeated queries.

Other issues were related to delayed completion of CRF (e.g., data entry was delayed for almost one year in some cases, thus query resolution was also delayed). Changes in principal investigators in some institutes occurred without proper handover and documentation. In addition, on the specific datapoint of efficacy, the follow-up data to treatment outcomes were missing; names of concomitant medication were missing and not reconciled; and safety database reconciliation was never performed.

The resulting delayed interim analysis was costly because the needed data for planned conference publications were not available. This postponed product launches and key opinion leader engagement activities.

Although it is acceptable for long-term studies to have a reduced number of visits, it is essential to have processes to continue to monitor the quality of the data that the studies are generating.

> Using innovative technology that is the personification of a well-trained, cost-oriented, and independent (human) quality checker in a complicated assembly line, but a hundred times better than any human, is no easy task.

Lack of Training

Since both were long-running studies in multiple countries in Asia, the Middle East, and Eastern Europe, several regulatory and pharmacovigilance changes occurred. Training related to new regulations, policies, and standard operating procedures (SOPs) was not implemented in real time at several clinical sites in different countries, which resulted in protocol deviations such as missed visit windows, noncompliance to study product intake, and inadequate safety reporting. Correcting these deficiencies required time-consuming and resource-intensive efforts. Lack of a proper training matrix and poor delivery of the existing training were at the root of this issue.[3]

Lack of Stakeholder Communication

Our analysis of the issues also revealed a lack of proper communication channels to not only address the issues, but to determine their severity. Had there been proper risk monitoring through quality tracking or oversight, the issues could have been identified and resolved in a timely manner.

A robust quality oversight system would have prevented the delays and increased costs experienced during both studies. By applying the spirit and concept behind the U.S. Food and Drug Administration's (FDA's) guidance on risk-based monitoring and the related European Medicines Agency's (EMA's) reflection paper, the study owner—a major pharmaceutical company—could have alleviated the situation by combining the right technology with trained personnel.

In 2012, the FDA encouraged "sponsors to develop monitoring plans that manage important risks to human subjects and data quality and address the challenges of oversight in part by taking advantage of the innovations in modern clinical trials. The FDA asserts that [RBM] could improve sponsor oversight of clinical investigations."[4] Further, in 2013, the EMA came out with its own views on RBM for quality purposes in clinical trials, in a paper that states the purpose is "to encourage and facilitate the development of a more systematic, prioritized, risk-based approach to quality management of clinical trials, to support the principles of Good Clinical Practice and to complement existing quality practices, requirements and standards. Quality in this context is commonly defined as fitness for purpose. Clinical research is about generating information to support decision making while protecting the safety and rights of participating subjects. The quality of

information generated should therefore be sufficient to support good decision making."[5]

While the intents of the FDA's guidance and EMA's reflection paper are similar, two major issues are noted with the adoption of the tenets of both documents: *interpretation and implementation.*

Depending on the functional structure of a sponsor's or CRO's project team, there is a shift from 100% SDV with frequent face-to-face interaction with a site team to a more targeted and less frequent approach to monitoring visits. The decision-making process on how to adopt the guidance hinges upon first tweaking conventional, proven, and tested processes (re-prioritizing the budgets that come with them), and then to assume that the expected outcome of the tweaked actions will yield the same result. Unfortunately, this is not the case.

Updating processes is not the only key that defines compliance with both the guidance document and the reflection paper. For the paradigm to shift, the mindset must change. Along with this change must come acceptance of the initial increase in cost to leverage new or already available technology.

The cost of change will not be readily visible until a few years down the line. In performing the root cause analysis and identifying the factors that contributed to the increase in cost and delay in completion of the studies mentioned earlier, it became more evident that it was only after the company decided to retrospectively review its processes and identify the gaps that things became more obvious.

The old adage of "learning from one's mistake" not only resounded clearly, but also highlighted the fact that in today's current clinical trial management environment, staying ahead and being first to market must take into account changing attitudes, refocusing on standardized training, increasing reliance on utilizing technology-savvy resources,[6] and reconfiguring budgets to include (during the start-up phase) technology that can do half the work for people who will be spending more of their time in-house or homebound versus continuing to work as "road warriors."

Quality Oversight Technology

Finding the technology these days that best suits what project teams need is like differentiating between wheat and rice noodles in a bowl of soup. Technology platforms from different vendors have major similarities in vision, and all promise to track and trend in as close to real time as possible.

Using innovative technology that is the personification of a well-trained, cost-oriented, and independent (human) quality checker in a complicated assembly line, but a hundred times better than any human, is no easy task. The sponsor is the best stakeholder to utilize such technology, since other than the patient, the sponsor is the most impacted by delayed clinical trials and consequent increase in budget allocation.

The ability of the sponsor's clinical research team to use, at any time of the day and night, their smart phones or tablets to check the status of their studies in real time is to this day still in question. The goal of being able to rely on technology to see the number of queries, or patients enrolled, or risks identified and graded, as well as the cost for each activity and the site's actual performance remains on the project team's wish list. To date, project teams are still dependent on reports being spit out by data management or study management systems purchased by their companies, or must rely on Excel spreadsheets as their backup.[7]

The questions remain: How can innovative treatments be made available faster and improve the trends toward disease management? How do we ensure that both data quality and the means of collection are reliable?

With a new political administration in the U.S. and with forecasts of deregulation in the FDA[8] leading to faster cheaper drug development, a system that functions as an independent quality and risk tracker may be needed more than ever to ensure the "no blind spots" mentality. Any risks or quality issues detected compromise clinical trial safety and efficiency without timely responses. Hence, such a system should be configured to be able to track and trend issues in as close to real time as possible. Company and site processes will need to be reviewed and enhanced to adapt to the changing landscape.

There is an opportunity for the FDA to once again focus on its mission of ensuring that patients have access to better drugs faster and at lower cost.[9] For years, the agency appeared risk averse, because it is answerable to Congress and the public when risks of adverse side effects from approved drugs become apparent.

FDA's risk aversion converts to complicated regulations that contribute to delays due to lack of resources at sites to comply with the regulations, or due to failures to fully understand the intents of the regulations on the parts of clinical trials teams. Meanwhile, as the clear victims of side effects are accounted for, those patients who have yet to access or even know of better drugs to improve their lives remain mostly unidentified. Who can quantify the loss of life or diminishment in quality of life due to delays in terms of improved treatments reaching market?
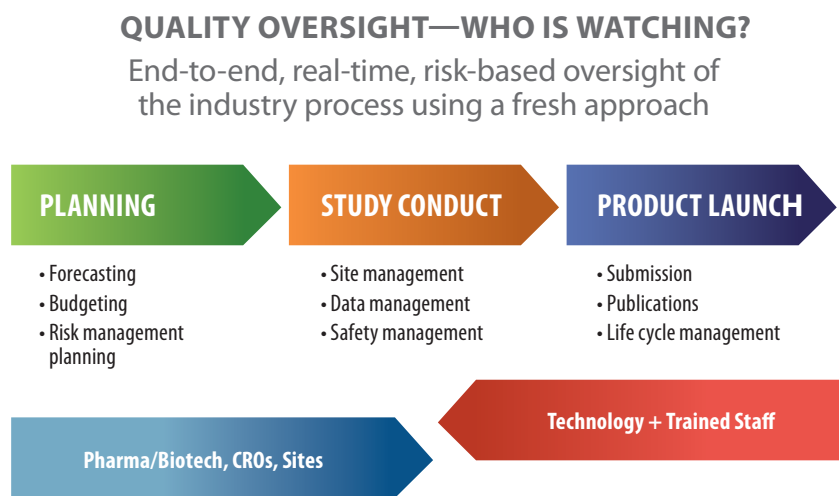
The prevailing cost of a clinical trial program for the development of a single new drug could range from millions to billions of dollars.[10] Only the big pharmaceutical companies will long be able to manage this because they have the resource, but even these firms are complaining; their investment must translate to bigger returns, thus costlier drugs.[11] The ones who are excluded from the big trials are the small, innovative pharmaceuticals and biotechnology companies, and it is difficult for them to compete due to cost; however, they could be the source of life-improving drugs and devices.

Quality and Risk Oversight Tracking (QROT)

QROT[12] is the use of Big Data analytics and patient-centric solutions that are transparent, and that promote integrity with the ultimate goal of bringing medicines swiftly to patients at affordable prices (see Figure 2). The industry's tradition of using mostly batch data transfers is not effective in helping improve data-driven decision-making abilities. With QROT, however, tracking quality and risk indicators (including financial data from enterprise solutions) in real time is very valuable in assessing cost and performance of projects any time of day or night in smart devices.

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FIGURE 2: Quality and Risk Oversight Tracking

QUALITY OVERSIGHT—WHO IS WATCHING?

End-to-end, real-time, risk-based oversight of the industry process using a fresh approach

PLANNING
- Forecasting
- Budgeting
- Risk management planning

STUDY CONDUCT
- Site management
- Data management
- Safety management

PRODUCT LAUNCH
- Submission
- Publications
- Life cycle management

Technology + Trained Staff

Pharma/Biotech, CROs, Sites

This QROT concept is further exemplified by the Quality Management Institute, which ascribes to having a "Zero Defect Attitude."[13] As applied to the process of QROT, this attitude means that having "pride of workmanship" leads to people doing things right for the client, and delivering as close to what was promised as accurately as humanly possible. Adopting a "Zero Defect Attitude" empowers project teams to focus on using solutions that can diminish possible deficiencies.

Conclusion

Relating back to the case studies presented, the lack of quality oversight resonated from all the deficiencies identified. The underlying thought that followed was the need to avoid having the same problematic issues arise again and again.

The owner of the studies eventually embarked on trying something different; using the outcomes from the root cause analysis as a tool to defend the study budgets and to secure the use of a new technology for quality risk oversight that tracked and trended data as they came in.

Two new, smaller scale studies were launched. This time, the project team used the information from the systems dashboard to closely monitor the progress of the studies. In the process of having a more robust and updated tracking of how the studies were doing, they were also able to enhance their SOPs, propose the continued use of the technology for quality risk oversight, and justify more training for their project team.

After 12 months, these two new studies had clear outcomes in terms of finishing on time and within budget, and more importantly, being available for publication per the targeted date. No more blind spots were noted after adequate tracking had been initiated.

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

PEER REVIEWED

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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]

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

A critical barrier to clinical trials is inconsistent—or even absent—competency-based training for all study personnel involved in clinical trials.

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.

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.

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

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

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.

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OPINION:

The Role of Certification in Developing a Quality Clinical Workforce

"Quality" is a term that is thrown around at will when speaking about clinical research—we speak of quality by design, quality systems, quality endpoints, quality management plans, quality data, quality outcomes, etc. We have been talking about quality for as long as I have been involved in clinical research, and that has been for more than 20 years.

> The goal of certification is not to educate, but to provide a means by which proficiency and knowledge can be measured, hence measuring "quality."

One thing I've noticed in the clinical research enterprise is that we spend a lot of time focusing on quality goals, quality outcomes, and quality processes, yet we spend very little time focusing on "quality resources" and—in particular—"quality human resources." I would like to focus our attention in this article on the importance of the "quality clinical workforce."

As used in various situations, the word quality may convey the standard of something as measured against other things of a similar kind; the general degree of excellence of something; or a distinctive attribute or characteristic possessed by someone or something. As nebulous as these uses may be, how do we measure quality when we are speaking about the "workforce" or human resources? That is where certification comes in, as certification is a formal recognition of professionals who have demonstrated the knowledge, skills, and abilities to perform their duties by passing a certification exam based on international standards.

Further, certification is a voluntary process to recognize individuals for meeting standards in terms of their professional experience, and for achieving educational requirements before taking the exam. Certification assures the public that an individual demonstrates specific knowledge required of a practitioner at a certain level. The goal of certification is not to educate, but to provide a means by which proficiency and knowledge can be measured, hence measuring "quality."

Why Certification?

There are some obvious benefits to an individual from becoming certified (see Figure 1). Achieving certification demonstrates that you have met or exceeded the quality standards required in the industry and have validated your competence. It furthermore demonstrates a level of professionalism and indicates a commitment to quality standards.

In essence, certification defines you as a "quality resource" in your industry. As specifically considered within the clinical research enterprise, there are many pros to certification, including how it improves the conduct and public perception of research by establishing and continually raising the levels of quality to which we are held. More pointedly, sponsor companies and study sites are able to use certification as a yardstick by which they can have their quality resources assessed and measured.

Sources of Certification

Currently, there are several organizations that offer clinical research certification. To date, the Association of Clinical Research Professionals (ACRP) is the only organization that offers role-specific certification programs (through its affiliated Academy of Clinical Research Professionals) for the clinical research coordinator (CCRC®), clinical research associate (CCRA®), and principal investigator (CPI®)

roles, as well as a general certified professional (ACRP-CP®) program since 2017 for anyone who does not neatly fall into the other roles.

Other organizations, such as the Society of Clinical Research Associates, offer more generic certifications covering multiple roles and functions. Many other organizations offer various types of role-specific certifications such as the Society for Clinical Data Management, the Society of Quality Assurance, the Clinical Research Society, and the Regulatory Affairs Professionals Society, to name a few.

Any respectable organization that offers certification will take the steps necessary to ensure that certain levels of quality have been achieved through their programs. Although ACRP may have led the way in the certification of clinical research professionals, there have been other organizations that have followed—not because any higher authority mandated it, but because their members asked them to.

In time, perhaps regulatory stakeholders around the world will also embrace certification as a quality measurement, and will deem that certification of anyone performing clinical research activities be required. This may be "pie in the sky" thinking, but it would go a long way toward making our study volunteers feel confident that they are being protected and are in "good hands."

Maintenance of Certification

For those of us who have achieved certification, equally as important is the subsequent maintenance of the designation. Throughout our careers, we want to continue to demonstrate that we are meeting or exceeding the quality standards set by the industry. Maintenance can be achieved through continuing education in both research- and healthcare-related subjects, as well as through continuing involvement in clinical research activities.

Since most individuals would prefer not to have to take a certification exam over again following a lapse in their certification status, the option for continuing education and continuing involvement is the more popular one, and the benefit to the industry is the assurance that certificants are staying abreast of the latest and greatest trends and topics in clinical research. In short, maintenance of certification validates that certificants continue to demonstrate their knowledge and skills as their careers progress (see Figure 2).

FIGURE 2: MAINTENANCE OF CERTIFICATION

Maintenance
- Ongoing validation of knowledge and skills
- Keeps current with changes in industry

Certification
- Baseline assessment of key competencies
- Reflects current practice

Knowledge and Skills

FIGURE 1: REASONS BEHIND CERTIFICATION

22.9% Validates Job-Specific Competencies

19.4% Promotes Professional Standards

18.4% Indicates Profession Growth

14.6% Job Mobility

14.1% Personal Accomplishment

6.8% Employer Requirement

Source: Survey of ACRP Certificants (January 2013 - April 2014)

Average Amount of Total Study Grants Invoiced in 2013

Average Reported Operating Profit in 2013

Average Number of Clinical Trials Initiated in 2013

$1,613,281

$466,690

18.2%

13.9%

20.9

6.9

Fewer Certified Staff More Certified Staff

Source: CenterWatch/ACRP Site Benchmarking Survey (2014)

Linked to Fewer Protocol Deviations

CCRC® and CPI® certification have the potential to increase protocol adherence and improve clinical trial quality through links to fewer protocol deviations (*Clinical Research and Regulatory Affairs,* 2009).

Linked to More Favorable Outcomes from Regulatory Audits

A positive correlation exists between the CPI® designation and favorable outcomes (No Action Indicated) for FDA audits according to the article "CPI® Certification as Predictor of Clinical Investigators' Regulatory Compliance" (*Drug Information Journal,* 2012).

Other Considerations for Certification

As the clinical research industry has become more competitive, the need for its professionals to differentiate themselves from one another has become a more cogent reality. The use of credentials to demonstrate certification has become increasingly important when trying to promote one's curriculum vitae to the top of the pile.

Unfortunately, there has been some rather negative press regarding resume fraud, and one recent, controversial article cited that, out of more than 40,000 CRAs being captured by one recruitment firm, approximately 17% had falsified all or part of their resumes. As a hiring manager in the industry, I too have witnessed my share of "creative writing" when it comes to prospective applicants. This is where certification can play a role in ensuring that those applicants presenting with the credential of "certified" can be held accountable to a higher level, and employers can be assured of a standardized level of quality.

ACRP takes the use of its credentials very seriously, and has strict policies pertaining to the continued use of the "certification credential." Anyone who fails to maintain their certification must immediately stop using the credential to promote

himself or herself. In fact, misrepresentation of one's certification status through ACRP is grounds for disciplinary action through the aforementioned Academy of Clinical Research Professionals, according to its "Code of Ethics and Professional Conduct" policy.

This, once again, points to the fact that certification is formal recognition of professionals in the industry who perform at or above a certain quality standard. Prospective employers and regulatory inspectors can search a registry to ensure that anyone using the ACRP credential is actually currently certified. Falsifying credentials is a serious blemish when it comes to tarnishing one's quality reputation, and no one wants that.

Getting back to the issue of "quality," it has been demonstrated that certification through ACRP has a positive impact on clinical trial quality surrogates, such as stated at left. From the sponsor's perspective when looking at potential sites, quality plays a role. Studies have shown that having certified staff at a site leads to fewer protocol deviations and potentially increases trial adherence, and that a positive relationship can be seen between a certified PI and more favorable audit outcomes with the U.S. Food and Drug Administration (FDA).

From a site's perspective, we can see a positive relationship between the number of certified staff and the number of study grants received, the operating profit achieved, and the number of clinical trials initiated (see Figure 3). These site performance metrics are all very important when trying to attract studies to your site; certification can therefore be seen as an investment in the professional development of a site's research personnel and the site's commitment to quality in the conduct of clinical trials. The return on investment for a site from having certified staff can be easily demonstrated.

Furthermore, certification can be used as a proxy for improved outcomes, which can be demonstrated through adherence to the protocol, compliance with the regulations, ethical practice, trial subject safety, and ultimately end-consumer safety. With respect to our quality clinical workforce, certification can be used as an acceptable method to validate that study coordinators, monitors, investigators, and other clinical research professionals have the knowledge, skills, and abilities fundamental to accomplishing their job roles.

As the arena of certification products offered through various organizations expands, there is a recognized need for more formal study of the impact on quality from the perspective of the site, the sponsor, and ultimately the patient. For now, the ship is moving in the right direction.

Conclusion

Now that we know what a quality resource is, we can measure that quality through certification. We also can demonstrate continued commitment to quality through maintenance of certification, and we are now moving to a more data-driven place whereby we can demonstrate improvements in quality through the use of "quality human resources."

Certification can be a valuable resource for a variety of stakeholders to validate that the clinical research professionals with whom they are engaging—in whatever relationship that may be (i.e., site-sponsor, sponsor-employee, site-employee, etc.)—have the knowledge, skills, and abilities fundamental to their role, and that they truly are a quality human resource and part of the "quality clinical workforce."

In a recent CenterWatch publication, ACRP Executive Director Jim Kremidas stated, "If you get your hair cut, the barber cutting your hair must have a license. In many parts of the world, if you join a clinical trial, the study coordinator doesn't need a license or to even be credentialed." He has a very good point; does it seem right that we place so little value on quality when it comes to clinical research?

To be sure, there are certain jurisdictions around the globe where qualifications for clinical research are taken more seriously. In some countries, for example, study coordinators must hold at least a bachelor's degree, but this is not universal. Unfortunately, we have a long way to go to standardize these requirements on a global scale.

Ultimately, if we want to improve the quality of research, then industry needs to come together to make sure we have competent "quality resources" and a "quality workforce" conducting our clinical trials. There is an ever-increasing wealth of evidence as to why we need these quality human resources—among it, the fact that the equivalent of a bad haircut in clinical research can be deadly.

As the clinical research industry has become more competitive, the need for its professionals to differentiate themselves from one another has become a more cogent reality.

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REGULATIONS AND COMPLIANCE

Blind Spot in Clinical Trial Operations: Who is Watching?

LEARNING OBJECTIVE

After reading this article, participants should be able to explain the importance of quality oversight technology for clinical research, and to highlight several major factors behind insufficient study oversight.

DISCLOSURE

Nadina Jose, MD; Roshan Padbidri, MS; Suzette Cody, MA: *Nothing to disclose*

1.   According to the article, the assumption that all clinical research stakeholders are paying attention to a trial's progress and risks fails due to which of the following factors?
A.   Each stakeholder only focuses on the part of the trial that is most expensive for them.
B.   Only the regulatory authorities really need to be involved in tracking trial activities.
C.   Information overload complicates everyone's capacity for real-time issue tracking.
D.   Time differences and cultural customs across international studies complicate communications.

2.   Which of the following are consequences of trial issues being reported later than ideal?
1. Unattended queries leading to data management discrepancies
2. Projects experiencing delays and increased study budgets
3. Regulatory authorities conducting background checks on investigators
4. Waiting patients losing timely access to treatments

A. 1, 2, and 3 only
B. 1, 2, and 4 only
C. 1, 3, and 4 only
D. 2, 3, and 4 only

3.   Among other issues, delays in the two studies featured in this article were tied to which of the following concerns?
A. Staff turnover, serious adverse events, and protocol amendments
B. Site technology, budget overruns, and investigational product quality
C. Sponsor fraud, patient recruitment, and language barriers
D. Vendor oversight, staff training, and unresolved queries

4. According to the article, which of the following is a key factor in monitoring long-term studies?

A. Availability of adequate supplies for a monitor's visits

B. Ongoing data quality monitoring processes

C. Up-to-date technology for risk-based monitoring

D. Retention of study subjects using incentives

5. Reasons cited for failure to implement real-time training in the article's focal studies include which of the following?

1. Poor delivery of existing training

2. Lack of a proper training matrix

3. Obsolescence of training materials

4. Legal barriers to mandating training

A. 1 and 2 only

B. 2 and 3 only

C. 3 and 4 only

D. 1 and 4 only

6. The article mentions encouragement for studies to utilize risk-based monitoring strategies coming from which sources?

A. The European Medicines Agency and U.S. Food and Drug Administration

B. Contract research organizations and international study sponsors

C. Patient advocacy groups and case report form vendors

D. The International Council on Harmonization and Office for Human Research Protections

7. According to the article, when will the cost of suggested changes to study oversight processes become evident?

A. Immediately upon their implementation

B. Within a few months of their implementation

C. Several years after their implementation

D. At least a decade following their implementation

8. The article cites which stakeholder in clinical research as the best to utilize quality checker technology?

A. The lead study coordinator at the site

B. The monitor who visits the site

C. The remote monitor for the site

D. The sponsor of the study

9. According to the article, technology for independent quality/risk tracking may be needed due to which of the following?

A. Expectations that regulatory authorities will mandate its use in clinical trials

B. Effects from potential deregulation in the U.S. Food and Drug Administration

C. Pressure from sponsors to downsize study site staff devoted to such tasks

D. Desire among study site leaders to impress potential study participants

10. Quality and risk oversight tracking uses which of the following?

1. Vendor-supported software

2. Subject matter experts

3. Patient-centric solutions

4. Big Data analytics

A. 1 and 2 only

B. 2 and 3 only

C. 3 and 4 only

D. 1 and 4 only

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

LEARNING OBJECTIVE

After reading this article, participants should be able to identify the different online training platforms available and understand the benefits of continued training.

11. **According to the article, what are the possible consequences of inadequate training?**
    A. Poor understanding of the protocol, demotivated staff, low recruitment
    B. Delayed start-up, poor data integrity, compromised participant safety
    C. Large number of data queries, incorrect enrollment, incomplete case histories
    D. Inadequate drug accountability, lack of transparency, compromised results

12. **Which two platforms provide an introduction to the clinical research environment and regulations?**
    A. NIH and CTSA
    B. NIH and CITI
    C. NIH and ACRP
    D. CITI and ACRP

13. **What was the main purpose of the research discussed in this article?**
    A. To assess the quality of ACRP and CITI online training programs.
    B. To assess the quality of CITI and NIH online learning programs.
    C. To understand training needs of research staff at the site.
    D. To understand training processes of NIH and CTSA.

14. **What was the crucial step that had to be taken to enroll volunteers in the research discussed in the article?**
    A. Placing posters on campus.
    B. Sending e-mails to various mailing lists.
    C. Regulatory and IRB approval.
    D. IRB approval.

15. **Participants completed a randomly selected training module and, after a certain time period, then completed the alternate training and survey. What was this time period?**
    A. Minimum of one week
    B. Minimum of one month
    C. Exactly one year
    D. At their discretion

16. **What method was used to test for differences between the paired observations?**
    A. Confidence intervals
    B. Wilcoxon signed-ranks test
    C. Hypothesis testing and probability
    D. Correlation and linear regression

17. **Participants' responses were based on several variables. Four of these include:**
    A. Illustrated examples, reference to guidance documents, performance, cost of course
    B. Relevance to role, amount of information, technical difficulties, design of the course

C. Engaging, ease of navigation, scenario satisfaction, hours to complete course
D. Core concepts, resources, flow of information, technical language used in course

18. **Participants' time to complete the courses was calculated statistically. What was the mean for both courses?**
A. 2.3 hours (ACRP) and 3.26 hours (CITI)
B. 3.26 hours (ACRP) and 2.3 hours (CITI)
C. 2.5 hours (ACRP) and 3.0 hours (CITI)
D. 3.0 hours (ACRP) and 2.5 hours (CITI)

19. **From the four themes that emerged, self-evaluation refers to:**
A. Expressing predisposition to one of the platforms
B. Identifying key performance indicators
C. Assessing personal skill level
D. Meeting personal goals

20. **What were the greatest differences noted between the training platforms?**
A. Test methods, current updates, guidelines used, and content
B. References to guidance documents, tasks assigned, relevant information
C. Content relevance, organization, applicability, and assessments
D. Current information, use of technology, and validation scales

OPINION: The Role of Certification in Developing a Quality Clinical Workforce

LEARNING OBJECTIVE

After reading this article, participants should be able to discuss how certification can be used as a measure of quality.

DISCLOSURE

Kelly M. Cairns, MA, BASc, APRM, CCRA: *Nothing to disclose*

21. **The author expresses in the article that not enough focus is given to:**
A. Quality policy manuals
B. Quality human resources
C. Quality outcomes and processes
D. Determining root cause of quality issues

22. **What is the general understanding of the word "quality"?**
A. It refers to a standard for auditing clinical trials.
B. It is a standard of uniformity to ensure compliance.
C. It means maintaining high standards in a project.
D. It refers to a general degree of excellence.

23. What is certification?
   A. Attending and completing a course at a reputable institution.
   B. Obtaining a certificate after successfully passing an exam.
   C. Obtaining a certificate upon completion of a learning module and a certain number of certificates makes up a certification.
   D. Formal recognition of individuals who demonstrate knowledge, skills, and ability to perform their duties.

24. What is the goal of certification?
   A. To confirm that all individuals in research followed a standard of training.
   B. To ensure qualified professionals are involved in clinical research.
   C. To provide a means of measuring proficiency and knowledge.
   D. To comply with educational requirements of institutions.

25. How is certification beneficial to the industry?
   1. It may be used as a yard stick to measure and assess quality resources.
   2. It involves continually adjusting standards of learning to align with ICH GCP.
   3. It improves the conduct and public perception of research.
   4. It ensures that quality standards are met.

   A. 1 and 3 only
   B. 2 and 3 only
   C. 2 and 4 only
   D. 1 and 4 only

26. While several organizations offer clinical research certifications, ACRP has role-specific programs. What are these?
   A. CCRA, CCRT, CPI, CP
   B. CCRA, CCRC, ACRP-CP, CPI
   C. CCRC, RQAP, CPI, FACRP
   D. CCRM, CPI, CCRA, CCRC

27. What was the driving factor for organizations to develop and offer certification programs?
   A. Members demanded such programs.
   B. They are a regulatory requirement.
   C. A new industry standard designed to align with risk-based monitoring.
   D. ICH GCP states all individuals must be qualified by education and training.

28. How does industry benefit from certification maintenance?
   A. May be used as a means to measure quality.
   B. Demonstrates an individual's ability to follow through on tasks.
   C. Reduces the cost of having to sit for the certification exam again.
   D. Provides assurance that certificants are updated on the latest in research.

29. Prospective employers can confirm the use of ACRP certification credentials by:
   A. Reviewing individuals' Curriculum Vitae.
   B. Requesting certified copies of the certificate.
   C. Running a search on the ACRP registry.

D. Contacting the human resources department at the sponsor company.

30. How are quality and commitment to quality measured?
    A. Through continuing education credits.
    B. From accurate reflection of credentials on e-mail signatures.
    C. With current and updated training records.
    D. Through certification and maintenance of certification.