Clinical Researcher
September 2018
HOME STUDY TEST
Clinical Trials Teamwork: Some Assembly Required

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Clinical Researcher—September 2018 (Volume 32, Issue 8)

PEER REVIEWED

Sponsor-Site Communication in Device Trials: Evolution of a Dedicated Field Clinical Organization Throughout Study Execution

Jennifer Krueger, MACPR; Carolynn Jones, DNP, MSPH, RN; Marjorie Neidecker, PhD, MEng, RN, CCRP

Successful study execution is essential for sponsors and physician investigators. A quality study ensures timely collection of study data to ensure accurate measures of safety and efficacy. This impacts current patients and, of course, future patients as a new drug or device is marketed and used.

Today's clinical studies are "costly, complex, and time-consuming."{1} Efforts toward streamlining the clinical research process are desperately needed.{2–4} While much attention has been given to simplifying the regulatory system,{5} sponsors themselves must be responsive and commit to internal organizational and process improvement to maximize study efficiency.

Device clinical trials are similar to drug trials, but with the added dimension of complex biomechanical and, as required, implant instructions. For instance, in the case of implanted pacemakers, special imaging and output data are required to ensure proper placement and operation. As patients are enrolled, large amounts of data are collected which can lead to queries and delays in the final study report.

In keeping with new initiatives to streamline and bring efficiency to the clinical research process, the device manufacturing employer of the lead author of this paper changed the way it partners with study sites by creating a Field Clinical Organization (FCO) tasked with communication, relationship building, and provision to sites of a single point of contact across departments

responsible for the study within the sponsor company. This paper describes the evolution of the FCO and results of a study site satisfaction survey for this new initiative.

The Roots of the Field Clinical Organization

In 1974, the medical device company of interest established the Field Clinical Engineer (FCE) role within the United States and Canada to be primarily responsible for technical support on Investigational Device Exemption (IDE) studies being conducted by its Cardiac Rhythm and Heart Failure (CRHF) clinical division. The CRHF product lines include implantable cardioverter defibrillators, pacing leads, pacemakers, among other cardiovascular devices.

During device implantation or use, the FCE attended the procedure and provided the physician with technical support to ensure the protocol was being followed and the data collection was accurate. In addition, the FCE would attend follow-up visits with the coordinator to provide assistance should the coordinator have questions surrounding the protocol and data collection requirements and to monitor device function electronically.

FCEs were instrumental to the in-house study team, as they were the face of the sponsor at the site during implants to provide support to mitigate errors and violations of the protocol requirements. The other members of the sponsor side of the study team, consisting of data managers, safety officers, and clinical research associates (CRAs), did not travel to many implants or study visits.

In 2010, the company created another team of individuals known as Field Clinical Site Specialists (FCSSs). Each FCSS was responsible for the clinical sites within his or her territory and for all clinical studies being conducted within CRHF Clinical Operations. The FCSS was developed to ensure that documents and protocol-required tasks were followed according to regulations, Good Documentation Practices (GDocPs), and the company's standard operating procedures (SOPs).

The FCSS provided support from the start of the clinical study (activation phase) through the end (closure phase). This would allow for a relationship to be built between site and sponsor that brought continuity and timely responses throughout the course of the study. In addition, the

FCSS would manage the clinical trial management system (CTMS) to track and manage regulatory documents received for the clinical studies.

The Field Clinical Organization

Ultimately, the FCSS and FCE structures within the U.S. and Canada evolved into what is now known as the Field Clinical Organization (FCO). In this system, FCEs and FCSSs partner within their territories (a one-to-one relationship) to become the primary point of contact for their research sites for any questions, case and technology support, or assistance with query resolution, to name a few activities.

The FCSS/FCE pairs work together to ensure the timelines of their studies are being met. It is extremely important to activate studies quickly and enroll well, but it is also essential to have clean data and to be responsive. The FCO structure ensures the study sponsor team's requests are being met by partnering with the research sites.

Roles and Responsibilities

From the site perspective, one valuable aspect of the FCO pairings being responsible for a territory is that it helps develop a relationship and familiarity with the sponsor representatives for all studies the site and sponsor complete together. It creates a bond where each is responsible for executing a clinical trial successfully because they own all phases of the study lifecycle. Thus, in the case of a site conducting more than one of the sponsor's studies within the CRHF Clinical Organization, the FCO remains the primary point of FCSS/FCE contact for that site. In addition, each FCO pairing is responsible for developing relationships with new clinical sites with which the sponsor becomes engaged in its territory.

The FCE is responsible for networking within the territory to better understand which sites and physicians are interested in clinical research with the sponsor. Because this role is territory-based, the FCE gains local knowledge about the sites and research personnel.

As clinical studies become available, the FCE/FCSS pairs are able to nominate suitable sites based on past experience in enrollment and quality and the investigator's interest in participating.

In addition, the FCE trains clinical site personnel on the protocol prior to activation. The FCE can also assist with the collection of documents or ask questions while onsite to help ensure study start-up is progressing.

Once a site is activated, the FCE attends implants and provides technical guidance to the investigator during the case (the FCEs are technically trained on the programmer, devices, etc.). In addition, the FCE works with the coordinator throughout the course of the study to answer protocol or query questions. The FCE remains the face of the sponsor throughout the lifecycle of the study.

The FCSS is also responsible for networking, but the FCSS's role is complementary to the FCE. Many FCSSs live within their territory; however, it is not required, as they can travel onsite when needed.

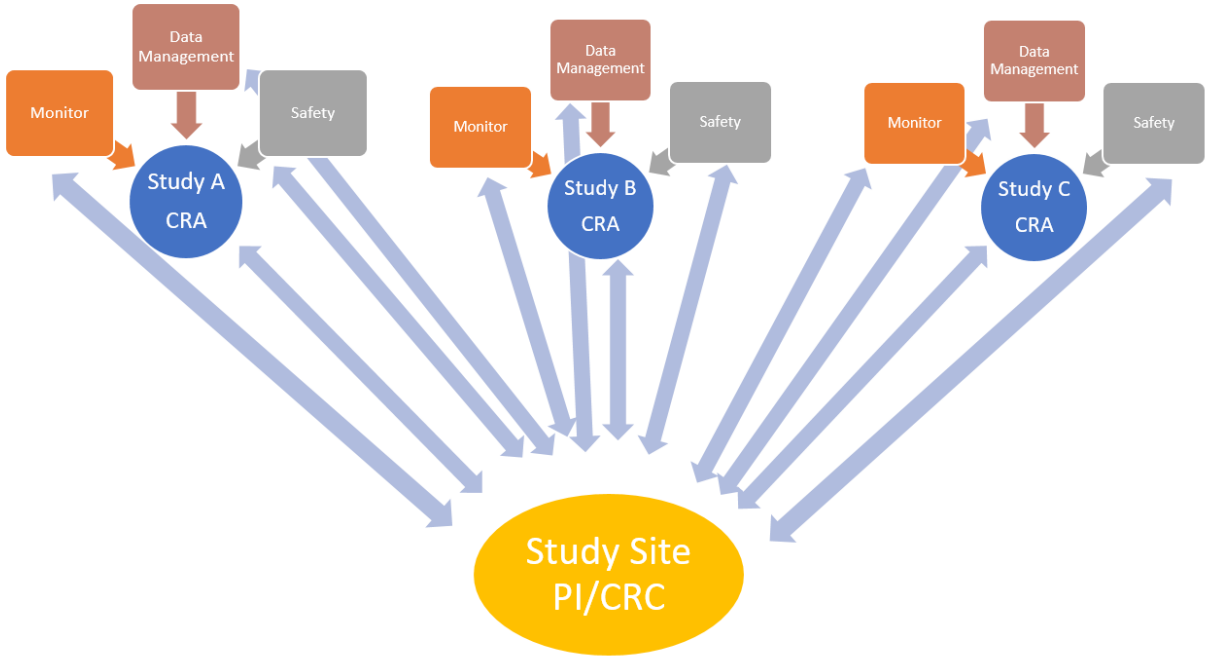
The FCSS partners closely with the FCE during the initial phases of the study, but the FCSS is instrumental in ensuring all components of activation are met as quickly as possible and are accurate per the regulations and internal SOPs. The FCSS communicates with the site when all activation requirements are met, and continues to provide support to the site by answering enrollment questions, supporting query resolution, and fielding protocol-related questions, to name a few activities.

When questions arise, it is not uncommon for the principal investigator or coordinator to contact both the FCE and FCSS by e-mail. Since the FCE has a technical background on the devices, questions pertaining to device implant or programming may go specifically to the FCE. However, questions related to data collection or the database may go to the FCSS because of his or her familiarity with the queries. Overall, it is beneficial for both the FCE and FCSS to be copied on all communications with sites, as it provides a broader awareness of discussions and decisions.

Figure 1 displays an example of the previous sponsor-site model in which each member of the sponsor's study team was responsible for contacting the site for requests and queries, which led to multiple points of contact and significant inconsistency amongst study teams in their communications with the site. Figure 2 illustrates how, in the current model, the FCO partners

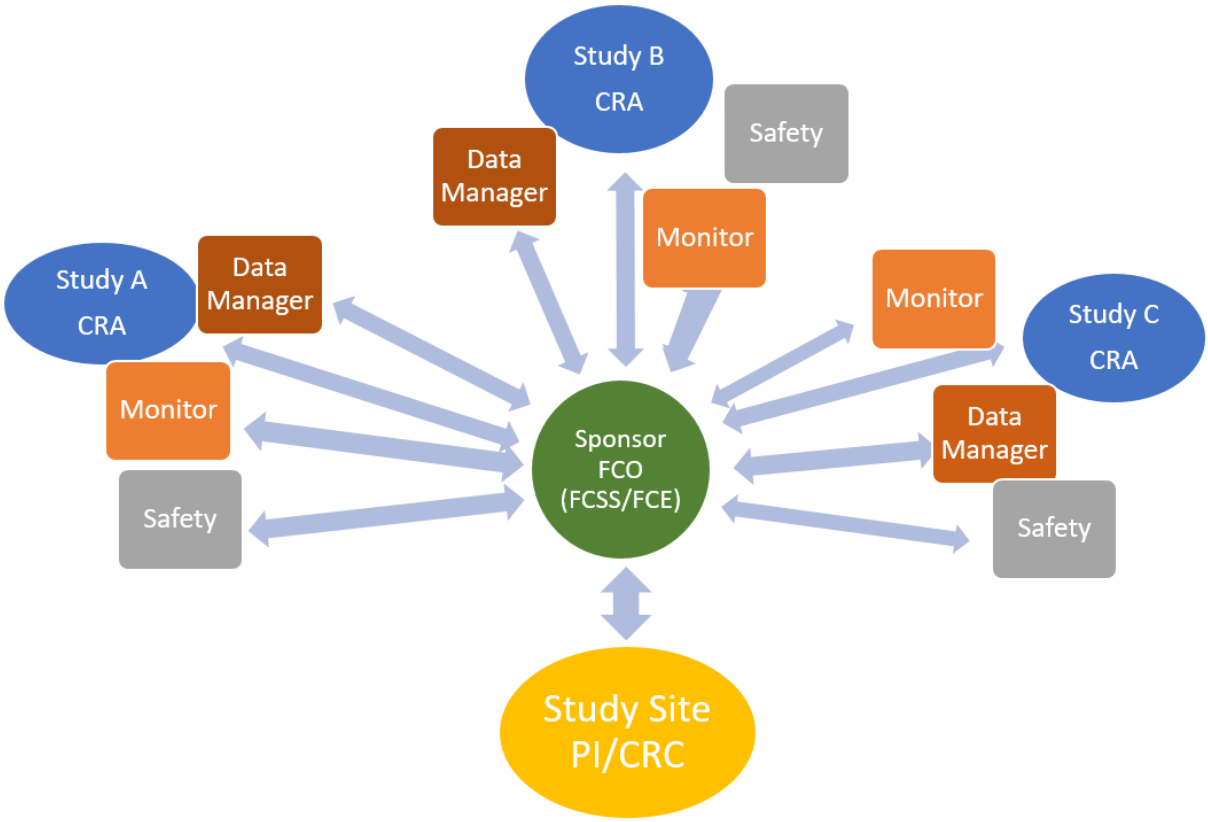
closely with in-house personnel and in turn transfers the information to the site. Because of this, communications to site personnel are streamlined and focused. Table 1 displays the responsibilities of the FCSS and FCE.

Figure 1: Traditional Sponsor-Site Model with Multiple Points of Contact



Note: CRA: Clinical Research Associate; CRC: Clinical Research Coordinator; PI: Principal Investigator

Figure 2: Field Clinical Organization Model (one primary point of contact at the sponsor organization)



Note: CRA: Clinical Research Associate; CRC: Clinical Research Coordinator; FCO: Field Clinical Organization (Includes Field Clinical Engineers (FCE); Field Clinical Site Specialists (FCSSs)); PI: Principal Investigator

Table 1: Roles and Responsibilities of the FCE and FCSS ***("X" denotes primary responsibility, but support is provided by both)***

Roles & Responsibilities	Field Clinical Engineer (FCE)	Field Clinical Site Specialist (FCSS)
Drives activation (includes the collection of investigator agreements, curriculum vitaes, delegation logs, IRB approval of informed consent and protocol, financial disclosure, etc.)		X
Protocol Training	X	
Case coverage	X	
Technical Training	X	
Regulatory Documents (create, review, verify)		X
Data Quality (e.g. query resolution & AE questions)	X	X
Payment questions		X
Inclusion/exclusion questions	X	X
Protocol related questions	X	X
Drives closure activities		X

Research Site Perspective

Metrics that the FCSS and FCE track include time to study activation, enrollment rate per month at the site(s), monitoring action items, and query resolution days.

While the FCO consistently strives to improve the days to activation, the number of days can vary from year to year, depending on the type of study (Investigational Device Exemption vs. postmarket) in the activation phase. From May 2017 until April 2018, the average number of

days for the FCO pairs to activate their sites in the U.S. and Canada was at an all-time low of 133 days, largely attributed to the FCO model structure.

Data on enrollment rate per month are tracked, but vary depending on site activations and number of active studies, and therefore enrollment outcomes are difficult to attribute to the FCO structure. This system supports the sponsor's query resolution goal of less than 30 days.

While the FCO method seeks to be both functional and efficient within the sponsor organization, its ultimate success is better judged by cooperating sites. The FCO pairs are responsible for partnering with both new and old sites, and in 2018, the FCSSs and FCEs were asked to circulate a satisfaction survey to their primary study coordinators in the U.S. and Canada who were supported by the FCO structure in June 2018.

A total of 65 surveys were distributed; 43 were completed and returned. Satisfaction scores were measures on those surveys that were completed. Overall satisfaction with the FCO was 97.6% by all research coordinators who completed the survey (90.20% extremely satisfied and 6.98% somewhat satisfied). For the FCSSs, 100% of those research coordinators were satisfied with their FCSS, while 87.8% were satisfied with their FCE. When asked if the research coordinators would prefer the FCSS/FCE model (one primary point of contact) as opposed to being contacted by each member of the sponsor study team, 90.2% chose the FCSS/FCE model.

These data validate confidence in the site satisfaction for this model. One survey respondent commented, "I feel that going to one point of contact was the best way for the organization to provide support to our study staff! We really appreciated this change!"

Challenges

While the attitude toward the FCO structure within the sponsor and with cooperating sites is overwhelmingly positive, the system is not perfect. One FCSS/FCE team may concurrently support 10 or more studies, which can lead to less familiarity with protocol requirements for specific studies. Therefore, the FCSS/FCE pairings can become the "middle man" as they ask members of the study team (including CRAs, data managers, safety specialists, etc.) questions on behalf of the sites and vice versa. However, a primary point of contact prevents sites from

becoming frustrated by wondering who to contact at the sponsor. As long as an answer is received in a timely fashion, the research coordinator and site personnel are satisfied, while the primary goal of providing exemplary service is upheld. In addition, the FCO is heavily focused on training to ensure team members are comfortable with delivering answers to questions to the sites.

Another challenge is that not all sites received the survey due to vacations or other unknown reasons. Therefore, the data may not represent the entire set of sites, thus introducing potential bias. Moreover, since this was a convenience sample, results may be inherently biased (e.g., highly satisfied coordinators may have been more likely to respond than those less satisfied).

Moving Forward

As the FCO initiative looks to the future, continuous self-evaluation is important. For example, the FCO model is currently only implemented within the CRHF Clinical Division at the sponsor. A possibility would be to implement this model within other business units to drive consistency across the greater company. Due to the success within the CRHF division, we feel there would be value to implementing this organizational process company-wide.

As the FCO continues to provide support to the clinical sites, we can look back and be pleased with the evolution of the FCO model and the clinical study execution each team member has provided. Moving forward, we hope to provide more best-in-class support to more studies, therapies, and clinical sites.

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Clinical Researcher—September 2018 (Volume 32, Issue 8)

PEER REVIEWED

The Use of a Blended Simulation Model to Increase the Confidence of Non-Clinical Personnel in Performing Clinical Tasks

Erin Prettiman, MSN, RN, ACNS-BC; Donamarie N-Wilfong, DNP, RN; Therese Justus McAtee, DNP, RN, CEN, TNCC; Laura Daniel, PhD

Vital signs, electrocardiograms (ECGs), and phlebotomy tasks have critical importance as the primary means to detect changes in patient condition and effectiveness of therapies. With such high-stakes decisions and assessments being made from these measurements and tasks, it is expected that they are completed with skilled proficiency. Typically, a practitioner with clinical training and experience, such as a nurse, fulfills these responsibilities. However, due to healthcare practitioner shortages and/or scheduling conflicts, many facilities rely on non-clinical research staff to perform these tasks, many of whom lack adequate knowledge or clinical practice of the procedures.

This article describes how a customized, clinical simulation–based course was designed, developed, and created specifically for the non-clinical audience. In this case study, a large, multi-hospital healthcare network in a metropolitan area lacked an adequate staff of nurses and/or phlebotomists to take vital signs, perform ECGs, and draw blood samples for various clinical trials and research projects. Therefore, leadership alternatively required that research coordinators fulfill these clinical responsibilities.

Most of the available coordinators lacked both healthcare education and previous clinical experience, but instead were trained in the world of business and/or research. Nonetheless the physician investigators of the studies quickly trained the research coordinators using the classic "see one, do one, teach one" method, and handed them a needle as they walked out to greet their first trial subject.

The informal training that the research coordinators received across the healthcare network lacked standardization, and varied greatly with time and with instructor. This off-the-cuff training was quickly deemed insufficient, as the managers reported many research coordinators felt under-prepared and/or anxious about their newfound clinical responsibilities even post-physician training. Therefore, managers from the research centers and the educational leaders from the network's simulation lab forged a new partnership to create dynamic healthcare training for this unique population of non-clinical personnel as part of their onboarding program. This training was not sanctioned by any hospital or the internal review board.

Methods

The newfound partnership between simulation and research managers allowed for the creation of an innovative educational approach to teach vital sign assessment, ECG tracing, and phlebotomy to this unique population through a blended learning model. This model consisted of didactic teaching followed by hands-on simulations and skill proficiencies using a standardized competency checklist.

Learners were guided through theory during the didactic portion of the course with an extensive PowerPoint lecture and class discussion. Instructors began this session by teaching learners the proper measurement methods of temperature, pulse, blood pressure, pulse oximetry, and pain. The instructors then taught the blood collection system—highlighting the significance of laboratory tests, specific collection tubes, and colors, and the proper procedure to preserve a collected sample, followed by a review of proper ECG placement identifying correct artifact.

Course instructors also weaved clinical documentation topics that highlighted legal implications for inappropriate documentation throughout the discussion. Instructors took great care throughout the lecture to avoid medical jargon and acronyms, assuming learners had no previous healthcare knowledge.

After the lecture, the learners practiced all the skills hands-on, using high-fidelity manikins and state-of-the-art task trainers as many times as they liked. Once they were satisfied with

their own practice, they were then evaluated by the course instructors to ensure competency in each of the three domains.

The participants were asked to demonstrate the proper procedure utilizing the requisite equipment to accurately measure and assess predetermined vital signs on the manikins; demonstrate accurate lead placement and tracing on an ECG task trainer; and draw blood samples. Course instructors used standardized competency skills checklists to deem learner competency. Each domain had its own checklist and the number of items varied on each: vital signs (48 items); ECG (20 items); and phlebotomy (28 items). These checklists required the course instructor to initial each item, verifying that she/he deemed the learner competent.

Furthermore, due to its invasive nature, participants were also given the opportunity to draw blood from live patients on clinical floors, under the supervision of an experienced phlebotomist. Learners were only permitted to partake in this experience after the course instructors deemed them competent on the simulators. These patients were research participants with the research institution.

The preceptor in the clinical setting provided learners with practical, timely feedback of their strengths and areas in need of improvement. If the preceptor in the clinical setting found a learner lacking proficiency in the clinical setting based on the competency checklist, that learner would be required to return to the simulation lab for remediation based on the preceptor's feedback. None of the participants required this retraining, and all participants were permitted to practice independently.

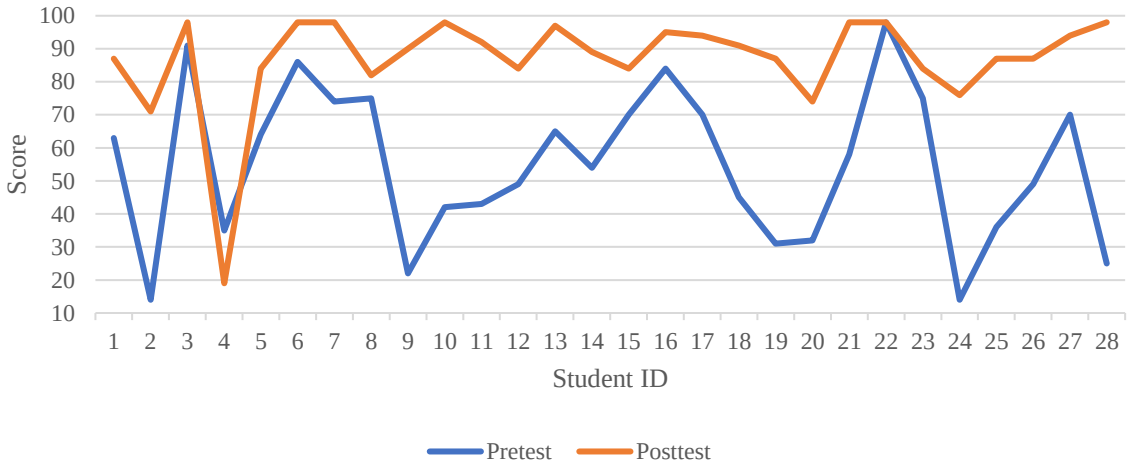
As a final synthesizing exercise, the learners participated in a simulated case study to practice and refine their critical thinking skills needed in clinical research projects. In this simulation, learners role-played an investigative drug study. The learners were asked to attend to a research subject and use their reasoning skills to determine how to accurately document a visit by the subject. This simulation gave the learners invaluable practice with the nuances and intricacies of a non-textbook documentation case.

Results

All course participants were deemed competent by the course instructors. None of the participants had to return to the simulation center for additional practice.

The course's pre/posttest asked learners (n = 29) to quantify how confident/unconfident they felt in fulfilling 14 job-related tasks on 7-point Likert scales, where higher scores represented more positive responses. These tasks covered the clinical aspects of their job responsibilities: phlebotomy process (5 items), taking vital signs (6 items), and interpreting ECGs (3 items). These items were created and vetted through an interprofessional panel of nurse educator, nurse manager, simulation expert, and psychometrician as they related to current job responsibilities to ensure content validity. Scores were summed across all items to obtain an index confidence score in fulfilling their clinical job responsibilities, with a possible range of 14 to 98. Students' individual pretest and posttest scores are shown in Figure 1.

Figure 1: Confidence Scores as a Function of Student and Administration Time



All but two students showed growth in clinical confidence after the course and thus all measures of central tendency increased after the course, as shown in Table 1. The variation in self-reported confidence scores also decreased after the training.

Table 1: Descriptive Statistics of Confidence Index Before and After Course

	Mean	Median	Mode	SD	Min	Max
Before	54.79	56.00	70.00	23.36	14.00	98.00
After	86.93	89.50	98.00	15.39	19.00	98.00

A Wilcoxon Signed Rank test was used to determine if students' (n = 28) self-reported confidence levels in successfully completing their clinical responsibilities changed after taking the course. Indeed, the test showed that there was a significant difference in the students' overall confidence levels before and after the course, $Z = 4.38$, $p < .01$. In fact, all 14 of the individual items also showed a significant difference in confidence ratings at the $\alpha = .05$ level of significance. SPSS 22.0 was used to conduct the descriptive and inferential statistics.{1}

Conclusion

This formal, competency-based simulation onboarding program for non-clinical personnel assigned to have clinical responsibilities empowered the employees with the competence and confidence needed to perform clinical tasks with proficiency. The educational investment afforded to the employees yielded benefits beyond themselves to the research subjects and to the larger research project. Research subjects experienced greater safety as more competent staff members drew their blood and assessed their vital signs. The research project experienced an increase in the reliability and validity of the data as staff members performed their tasks proficiently and identically.

This program demonstrates the applicability of simulation-based education to non-clinical populations. The blended learning model provided learners with time and education to grasp the theory behind the skills, and with hands-on simulation practice prior to any true research subject encounter. The simulation was self-directed, had immediate relevance to the learners' jobs, and was problem-centered, thus satisfying preferences of adult learners as stated in Knowles' 1984 theory of adult learning.{2}

Other hospitals and healthcare networks that are relying on non-clinical personnel to fulfill clinical responsibilities could model this onboarding program in their own institutions. Future research needs to extend this program beyond a single institution—gathering more participants and teasing out relationships between confidence levels and various independent factors, such as experience levels and education.

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SEPTEMBER 2018 CLINICAL RESEARCHER

HOME STUDY

Clinical Trials Teamwork: Some Assembly Required

Sponsor-Site Communication in Device Trials: Evolution of a Dedicated Field Clinical Organization Throughout Study Execution

LEARNING OBJECTIVE

After reading this article, the participant should be able to explain the development of the Field Clinical Organization (FCO), differentiate between the roles of the Field Clinical Engineers and the Field Clinical Site Specialists, explain the advantages of the FCO from the research site perspective, and describe the challenges for the FCO method.

DISCLOSURE

Jennifer Krueger, MACPR: *Stockholder and employee of Medtronic, plc*

Carolynn Jones, DNP, MSPH, RN; Marjorie Neidecker, PhD, MEng, RN, CCRP: *Nothing to disclose*

1. The Field Clinical Organization (FCO) was originally primarily responsible for technical support of:

a. IDE studies being conducted by the CRHF clinical division
b. All Phase 0 clinical trials
c. All post-marketing clinical trials (Phase IV)
d. All IND studies

2. The Field Clinical Site Specialist team was developed to ensure that documents and protocol-required tasks were followed according to regulations, the company's SOPs, and:

a. Good Clinical Practices (GCPs)
b. Good Manufacturing Practices (GMPs)
c. Good Documentation Practices (GDocPs)
d. Good Laboratory Practices (GLPs)

3. The Field Clinical Site Specialist provided support from:

a. Scientific review through IRB approval
b. The activation phase through enrollment
c. The activation phase through data safety monitoring board review
d. The activation phase through closure phase

4. Protocol training is the responsibility of:

a. The Field Clinical Engineer
b. The Field Clinical Site Specialist
c. Both the Field Clinical Engineer and the Field Clinical Site Specialist share this responsibility
d. Neither the Field Clinical Engineer nor the Field Clinical Site Specialist have this responsibility

5. Data quality is the responsibility of:

a. The Field Clinical Engineer
b. The Field Clinical Site Specialist
c. Both the Field Clinical Engineer and the Field Clinical Site Specialist share this responsibility
d. Neither the Field Clinical Engineer nor the Field Clinical Site Specialist have this responsibility

6. Payment questions are the responsibility of:

a. The Field Clinical Engineer
b. The Field Clinical Site Specialist
c. Both the Field Clinical Engineer and the Field Clinical Site Specialist share this responsibility
d. Neither the Field Clinical Engineer nor the Field Clinical Site Specialist have this responsibility

7. Inclusion/exclusion question are the responsibility of:

a. The Field Clinical Engineer
b. The Field Clinical Site Specialist
c. Both the Field Clinical Engineer and the Field Clinical Site Specialist share this responsibility
d. Neither the Field Clinical Engineer nor the Field Clinical Site Specialist have this responsibility

8. The quality of the protocol is the responsibility of:

a. The Field Clinical Engineer
b. The Field Clinical Site Specialist
c. Both the Field Clinical Engineer and the Field Clinical Site Specialist share this responsibility
d. Neither the Field Clinical Engineer nor the Field Clinical Site Specialist have this responsibility

9. Metrics that the Field Clinical Site Specialist and the Field Clinical Engineer track include:

a. Clinical trial costs
b. Time to study activation
c. Qualifications of the clinical trial staff
d. FDA observations

10. According to the satisfaction survey circulated in 2018:

a. Overall satisfaction with the FCO and the Field Clinical Site Specialists by the research coordinators was overwhelmingly positive.
b. Overall satisfaction with the Field Clinical Site Specialists was overwhelmingly positive while the satisfaction with the FCO was unacceptably low.
c. Overall satisfaction with the FCO was overwhelmingly positive while the satisfaction with the Field Clinical Site Specialists was unacceptably low.
d. Overall satisfaction with both the FCO and the Field Clinical Site Specialists was unacceptably low.

The Use of a Blended Simulation Model to Increase the Confidence of Non-Clinical Personnel in Performing Clinical Tasks

LEARNING OBJECTIVE

After reading this article, the participant should be able to explain the need for a blended simulation model to train non-clinical personnel to perform clinical tasks, describe the content of this clinical simulation course, explain the evaluation of the learners' competency within this course, and describe the outcomes of this course.

DISCLOSURE

Erin Prettiman, MSN, RN, ACNS-BC; Donamarie N-Wilfong, DNP, RN; Therese Justus McAtee, DNP, RN, CEN, TNCC; Laura Daniel, PhD: *Nothing to disclose*

11. The major reasons that many facilities rely on non-clinical staff to perform clinical tasks are:
a. The expense involved in using healthcare practitioners
b. Disinterest from healthcare practitioners to perform routine clinical tasks
c. Healthcare professional shortages and scheduling conflicts
d. Deprioritization of the importance of routine clinical tasks

12. The clinical tasks for which there is a shortage of healthcare professionals include:
a. Administering informed consent
b. Taking vital signs, performing ECGs, and drawing blood
c. Interpreting ECGs
d. Preparing a budget for performing clinical tasks

13. The classic "see one, do one, teach one" training method was deemed insufficient because:
a. It took too long to train non-clinical staff
b. The physician investigators didn't like the "see one, do one, teach one" training method
c. The "see one, do one, teach one" training method was too expensive
d. Many research coordinators felt under-prepared and/or anxious about their newfound clinical responsibilities even post-physician training

14. The sequence of training in this model consisted of:
a. Didactic teaching followed by hands-on simulations and skill proficiencies using a standardized competency checklist
b. Hands-on simulations and skill proficiencies followed by didactic teaching
c. Didactic teaching and hands-on simulations occurring simultaneously
d. The sequence was determined by each instructor

15. After the lecture, the learners practiced all the skills hands-on, using:
a. Clinical trials participants
b. High-fidelity manikins
c. Online simulations
d. Appropriate animal models

16. In order to evaluate appropriate skill level on the use of equipment, the learners:

a. Took an online simulation of using the requisite equipment accurately
b. Completed a written test on using the requisite equipment accurately
c. Orally explained the appropriate use of the requisite equipment
d. Demonstrated the proper procedure using the requisite equipment accurately

17. Due to the invasive nature of the required skills, the learners were given the opportunity to draw blood from:

a. Other learners
b. Live animal models
c. Live patients on clinical floors
d. The physician investigators

18. If the preceptor in the clinical setting found a learner lacking proficiency in the clinical setting, based on the competency checklists, the learner would be:

a. Required to return to the simulation lab for remediation
b. Removed from the program completely
c. Required to design their preferred remediation
d. Re-evaluated by another preceptor

19. What percentage of the participants required retraining?

a. 100%
b. 75%
c. 50%
d. 0%

20. As a final synthesizing exercise, the learners participated in a simulated case study in which they were asked to:

a. Attend to a research subject and use their reasoning skills to determine how to accurately document a visit by a subject
b. Write their own clinical laboratory order and execute it
c. Interview a physician investigator and critique his/her clinical competence
d. Design their own clinical trial and identify the training that would be required for non-clinical personnel to complete clinical tasks in the trial