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Clinical Trials Teamwork: Some Assembly Required

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Table of Contents

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

EXECUTIVE DIRECTOR'S MESSAGE

There's Room at the Table

Jim Kremidas

Think about the last special occasion you enjoyed at a favorite restaurant. Maybe it was a birthday. An anniversary. Or maybe you just decided to treat yourself to great food in a nice atmosphere with attentive and helpful wait staff.

Perhaps the host found you a nice corner table. The waiter may have suggested a personal choice about one of the specials. Later, the sommelier stopped by the table to give you some background on the seasonal wines on the menu.

If everything went smoothly, you benefited from a quality team of professionals functioning individually and together to produce excellent results.

Sound familiar? It should. Effective clinical trials are all about teamwork, too—on the parts of principal investigators (PIs), clinical research coordinator (CRCs), clinical research associates (CRAs), data managers, regulatory affairs specialists, institutional review board members, and many more. Clearly, clinical trials require a lot of moving parts and disparate skills to come together as a seamless unit.

I won't belabor the restaurant-clinical trial metaphor (Who's the chef? Who's the maître's d?), but I think it illustrates the point: As with any complicated operation, teamwork is vital in clinical trials.

Perhaps this is where the comparison ends, though. At that fancy restaurant, a weak link can mean a bad Yelp review, or at worst an inspection from the health department. During a clinical trial, a weak link can be far more serious.

Nothing "Soft" About It

Teamwork is what's called a soft skill, but it's actually very hard—hard to quantify, hard to demonstrate a tangible return on investment from, and hard to get right and keep right for prolonged stretches of time. However, common sense tells us stronger teams produce better results. In the clinical trial world, this translates into more efficient trials saving money and safely speeding critical and innovative drugs, devices, and therapeutic methods to patients who are anxiously awaiting new reasons for hope.

Just as the importance of teamwork cannot be overstated, so to is the value of industry-wide standards and certifications as an important foundation. CRCs, CRAs, and PIs are just three of the key components of a clinical trial. It's time for us to come together as an industry to further professionalize our outstanding workforce. We can raise the clinical trial industry to new heights if we band together to craft and implement a robust series of standards where, together, we are leveraging the latest best practices and tools in our day-to-day work.

As always, I welcome your thoughts. Please don't hesitate to reach out to me at the address below.

Jim Kremidas (jkremidas@acrpnet.org) is Executive Director of ACRP.

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

MANAGING EDITOR'S MESSAGE

Clinical Trials Teamwork: Some Assembly Required

Gary W. Cramer

Back in the days when the bread-and-butter part of one of my former jobs was translating the findings of scholarly research articles into digestible press releases for media consumption, one of my favorite topics was organizational behavior. Even for someone with as little business acumen as myself, it didn't take much to appreciate how insights on the eternal push-me/pull-me relationships between the management, production, and consumer sides of the goods and services triangle could be applied to other situations in life.

To me, what the business school researchers were tackling in their studies of employee dynamics in major corporations could just as easily have been about the people tied together through the work/audience environments with which I was more familiar—newspaper offices (editors/reporters, printers, subscribers), theater (backstage crew, onstage cast, patrons), and so on. To mangle more metaphors, every such environment lives and dies on the strengths of the teamwork relationships fostered between the three legs of the stool upon which it rests.

This is the lens through which I view the main articles collected in this issue of *Clinical Researcher.* Although on the surface, they may appear separately to focus on the discrete realms of device studies, non-clinical study staff, and principal investigators, each is really—to my way of thinking—about assembling portions of highly efficient clinical trials teams that benefit from the disparate talents of people with widely different backgrounds and perspectives.

All the Talents, All the Time

As put on display in these articles, in our clinical research enterprise, teamwork is not just something to be concerned about at the study site; it must encompass the coordinated efforts of

professionals from the sponsor/vendor, site, and participant sides of the triangle to deliver high-quality results. Yes, within a single part of this equation—a busy study site, for example—teamwork is key to keeping the clinical, non-clinical, and patient gears meshing smoothly, but to ignore the "assembly guide" best practices for keeping all the benefits of good communications, training, oversight, and reporting flowing between all onsite and offsite parts of the team would be an act of sheer folly.

What "lessons learned" have you experienced from your time with clinical trials teams? What tactics, cautionary tales, or recommendations for the good of the order are bubbling up in your psyche as our clinical research environment undergoes such rapid and ongoing evolution as it has in recent years? Please consider taking the time to share your thoughts and talents with your research colleagues through the many venues offered by ACRP, whether in the pages of this journal or a contributed blog for our website, in messages to the Online Community, in a webinar, in a presentation to an ACRP Chapter or conference, in participation with our new Partners in Workforce Advancement or Mentor Match Program, or by way of many other opportunities.

As always, many thanks for the critical work you do in your role on the clinical trials team. We look forward to hearing from you, and to helping you share your expertise on assembling this great project for the good of everyone.

Gary W. Cramer (gcramer@acrpnet.org) is Managing Editor for ACRP.

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.

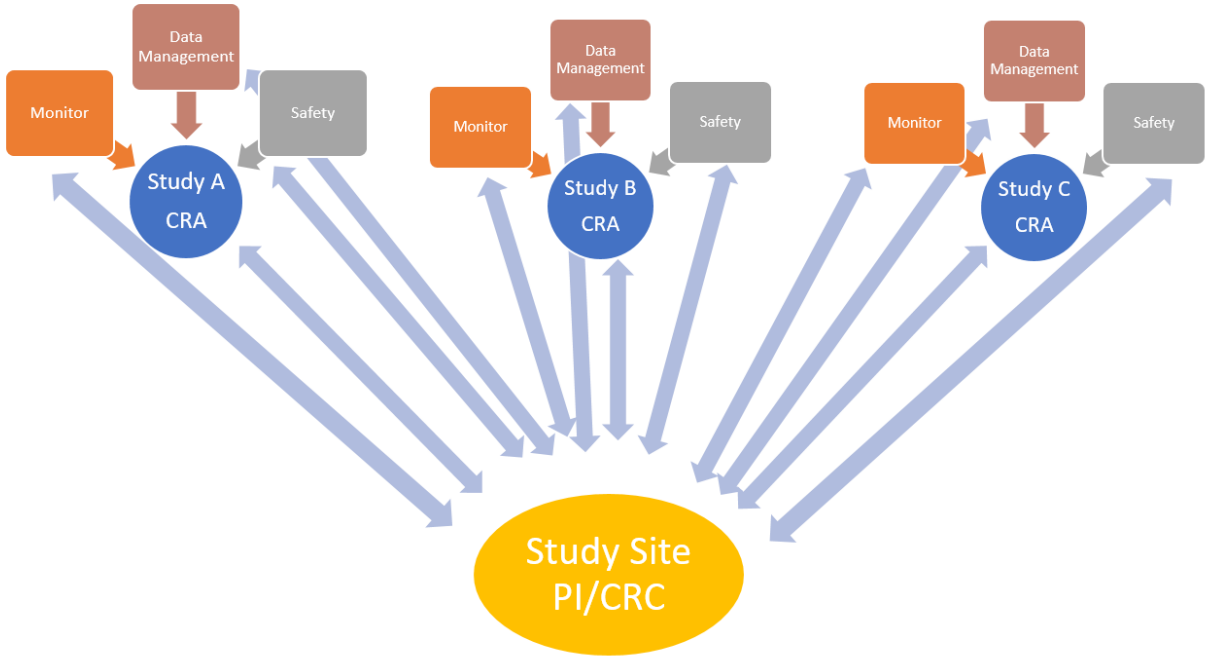
The FCSS partners closely with the FCE during the initial phases of the study, but the FCSS is instrumental in ensuring all components of activation are met as quickly as possible and are accurate per the regulations and internal SOPs. The FCSS communicates with the site when all activation requirements 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

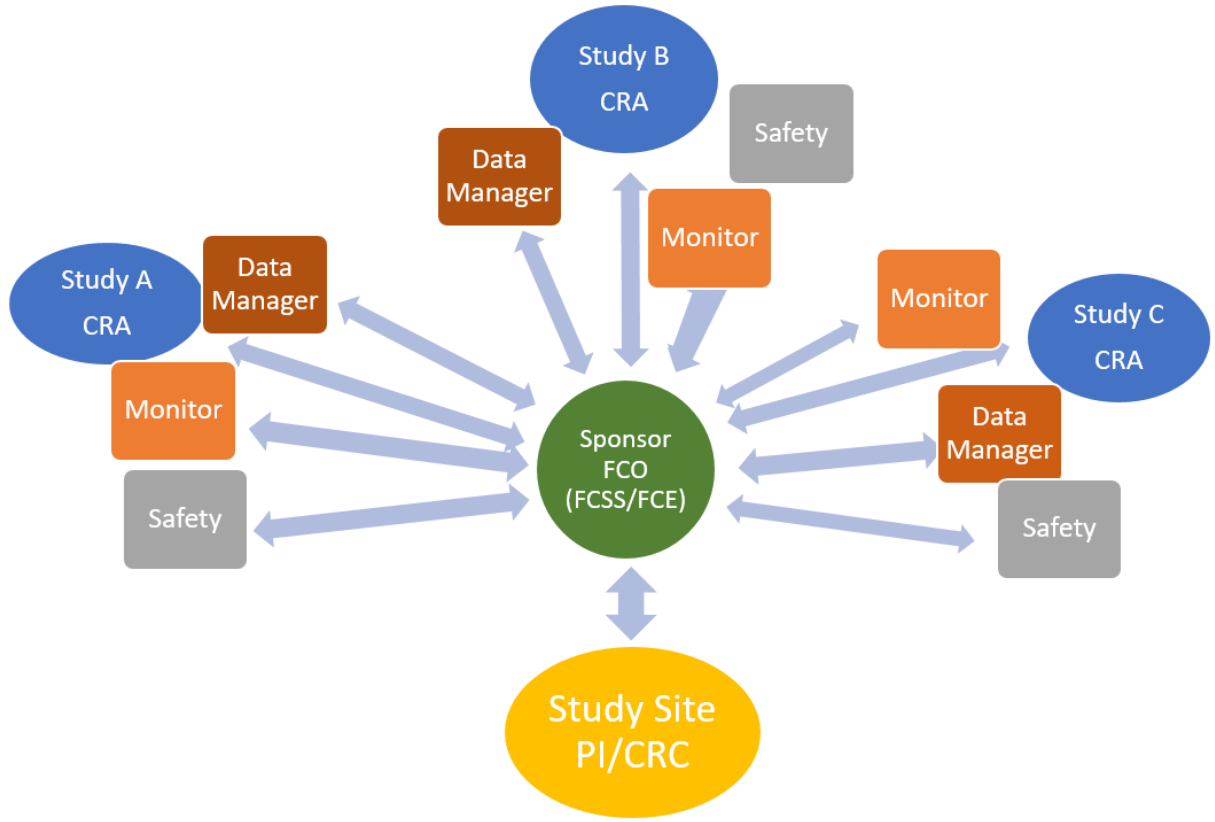
closely with in-house personnel and in turn transfers the information to the site. Because of this, communications to site personnel are streamlined and focused. Table 1 displays the responsibilities of the FCSS and FCE.

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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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.

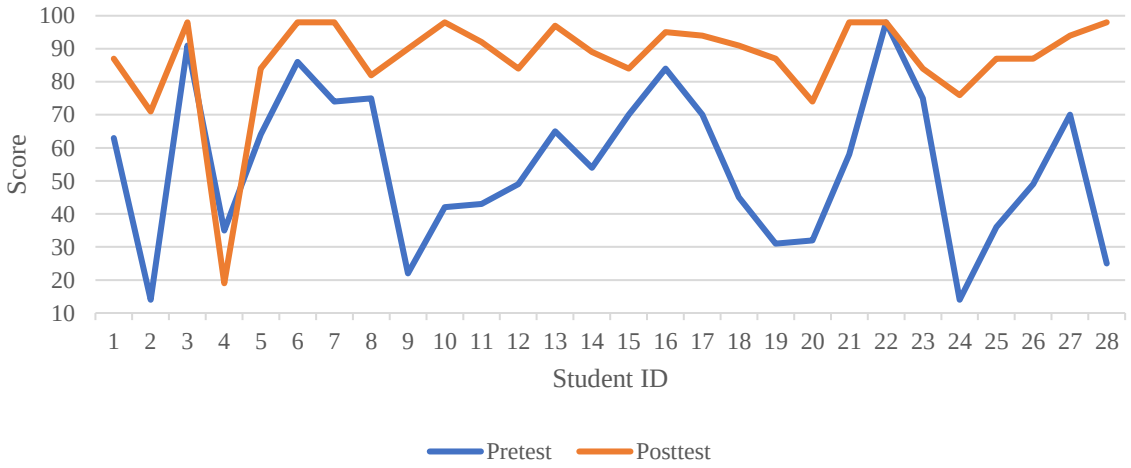
As a final synthesizing exercise, the learners participated in a simulated case study to practice and refine their critical thinking skills needed in clinical research projects. In this simulation, learners role-played an investigative drug study. The learners were asked to attend to a research subject 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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SPECIAL FEATURE

For Principal Investigators, the One-and-Done Syndrome Persists

Ann Neuer, MBA

Leon Rosenberg, a self-proclaimed physician-scientist at Princeton University and the former president of the Pharmaceutical Research Institute at Bristol-Myers Squibb Company, wrote a fascinating piece in *The Journal of Clinical Investigation* about the declining number of clinical investigators.{1} He declared, "In the absence of physician-scientists, the bridge between bench and bedside will weaken perhaps even collapse." The thing is, Rosenberg wrote this article nearly 20 years ago. Moreover, he reported that the number of clinical investigators was declining *even then*. In fact, he referred to them as an "endangered species," and perhaps he was channeling the future, given how strongly his words resonate today.

Current research suggests that this trend continues as clinicians who are principal investigators (PIs) routinely come and go in somewhat of a one-and-done fashion.{2} This was a key finding of a 2015 survey of 201 investigators, funded by the U.S. Food and Drug Administration (FDA) and the Clinical Trials Transformation Initiative (CTTI), in which 54.2% of respondents were classified as one-and-done.{2}

Similarly, a 2017 study from the Tufts Center for the Study of Drug Development (CSDD) found that the PI landscape remains highly fragmented, and is typified by heavy turnover, particularly among inexperienced investigators. To reach this conclusion, CSDD analyzed information from the Bioresearch Monitoring Information Database from 2008 to 2015, determining that half of all PIs filing a single Statement of Investigator form 1572 with FDA each year chose not to file again in subsequent years.{3} These results follow on the heels of earlier work from CSDD, which showed that in 2013, nearly half of the 40,000 global PIs were new to the job, suggesting ongoing turnover.{4}

Physicians are, of course, fundamental to the clinical trial process, but in an ever-more challenging clinical trial environment, what motivates them to become investigators and what is the industry doing to engage and retain them? What tactics are sponsors using to attract new PIs to the industry? These are important questions, as difficulties plaguing investigators have been widely reported—for example, in terms of trial conduct being more complicated due to tougher protocols, growing use of technologies and portals, greater regulatory scrutiny, and ongoing issues of financial viability at the site level. With this scenario, it is hardly surprising that investigators overwhelmed by their responsibilities in clinical trial conduct are heading to the nearest exit.

This article will explore:

- The status of the one-and-done syndrome—is it changing?
- What is needed for investigators to be successful and stay engaged in this industry.
- Steps a major pharmaceutical sponsor is taking to retain PIs and boost their chances for site sustainability.

Changing Direction

There is extensive and highly visible reporting on the challenges facing PIs, so it is worth asking what draws physicians into conducting clinical trials in the first place. Are they aware of the high barriers to entry? What about the need for infrastructure and an understanding of their responsibilities as defined by the internationally recognized tenets of Good Clinical Practice (GCP)?

David Morin, MD, FACP, CPI, FACRP, director of clinical research with the Holston Medical Group and a long-time PI, explains, "My 30 years of experience tell me that investigators who do this for the science are more likely to be successful in the long term. They want access to the next wave of treatments and to work with like-minded professionals. Financial motivation may play a role, but hopefully not the primary one."

Participating in research to help develop much-needed new treatment options for patients is a noble cause, and it offers personal and professional rewards. However, as Jeff Kingsley, DO,

MBA, CPI, FACRP, founder and CEO of IACT Health, points out, "Doctors get involved in research because they think it sounds great—like it's the right thing to do—but they have no idea how ill-prepared they are."

According to Kingsley, investigators discover that research takes dramatically more time than expected, involves volumes of paperwork, and too often, they choose protocols not well-suited to their practice. A growing body of research substantiates this claim; the FDA/CTTI survey, which explored the one-and-done syndrome, found a litany of reasons{2} (see Table 1 for the most common). These focus largely on the burdensome, time-consuming nature of clinical trial conduct and the inadequate clinical trial infrastructure in many physicians' offices. Still, there's more to the story; despite the difficulties, 44.4% of the one-and-done respondents reported that they are interested in continuing to participate in FDA-regulated studies, but they have been unable to find opportunities to do so.

Table 1: Drivers of the One-and-Done Syndrome (n = 93)

	Very Challenging	Challenging or Somewhat Challenging	Not Challenging
Workload Balance			
Finding time to devote to activities fostering promotion	44%	30%	16%
Long work hours	28%	64%	8%
Finding time to devote to other work activities (non-clinical)	28%	64%	6%
Time Requirements			
Amount of time required to prepare for trial start-up	28.8%	71.2%	0%
Amount of time required by investigator to support trial and site staff	28.8%	61.5%	9.6%
Amount of time required by staff to support the trial	26.9%	59.6%	5.8%
	Extremely Burdensome	**Moderately or Somewhat Burdensome**	**Not Burdensome**
Data and Safety Reporting			
Amount of safety data to report	32.7%	63.3%	4.1%
Frequency of reporting	29.2%	66.7%	4.2%
Amount of non-safety data to report	28.6%	67.3%	4.1%

Source: Adapted from Corneli A, et al.{2} 2017 under Creative Commons license.

While the one-and-done trend seems headed in the wrong direction, work toward a growing number of solutions to this dilemma is under way. Several organizations have stepped up to the plate with data highlighting this problem and strategies for moving the needle (see Figure 1). Most notably, there is a focus on training investigators to be aware of their responsibilities. Also, there is an emphasis on infrastructure to support PIs, not only in the form of technology, but also with staff skilled at handling the many business issues that are standard fare in study startup, clinical operations, and study execution.

Figure 1: Some Organizations with Efforts to Support PIs and Improve Infrastructure

- Academy of Physicians in Clinical Research (APCR)
- Association of Clinical Research Professionals (ACRP)
- Clinical Trials Transformation Initiative (CTTI)
- Drug Information Association (DIA)
- Model Agreements & Guidelines International (MAGI)
- Society for Clinical Research Sites (SCRS)
- TransCelerate BioPharma

In October 2017, CTTI published a report with numerous suggestions to address PI turnover and to strengthen the investigator community.{5} The broad-based suggestions are site- and sponsor-focused concerns, and are grouped into four categories:

1. Developing site-based research infrastructure and staff
2. Optimizing trial execution and conduct
3. Improving site budget and contract negotiations
4. Discovering additional trials to conduct

The recommendations highlight the multi-step process of launching a successful clinical trial, starting with selecting the right protocols, developing realistic patient recruitment and enrollment plans, and managing cash flow concerns. In addition, there is discussion on training for all site-level staff, including the sub-PI. Using this approach, the sub-PI learns the ropes before taking the leap to becoming a full-fledged PI.

Gerrit Hamre, a project manager for CTTI, notes that the recommendations are a starting point because, “There isn’t a lot of accessible information on the type of staff and infrastructure that investigators need—basically, the nuts and bolts. That’s where new PIs get tripped up, as it’s tough to get through the first several trials without that operational knowledge. One of our

recommendations is to start as a sub-PI along with some formal mentorship. That's a wonderful way for potential investigators to get their feet wet."

Similarly, Morin of the Holston Medical Group comments, "PIs at our site almost always start in research as a sub-investigator, which is a good way to get involved and begin to understand the process without ultimately being responsible for the trial. They work on about five studies as a sub-PI, and then transition when the right study comes along. Also, we have our own investigator training program and we mentor [them]. Once they become a PI, they are supported by a very experienced team of certified coordinators, a regulatory and financial/contract specialist, quality assurance monitoring, internal training, and a formal PI oversight process."

A Data-Driven Approach to Positive Change—A Look at Merck

In the midst of this industry turmoil, forward-thinking sponsors are listening and mobilizing as the *status quo* is no longer an option. In order to keep investigators engaged and nurtured so they can develop into excellent researchers, stakeholders are implementing data-driven programs to bring disruptive change.

Merck is one company that is taking some particularly bold steps. Jennifer Sheller, regional head for North America with Country Operations at Merck, explains that driving the firm's initiatives is the recognition that PIs alone cannot be expected to run all aspects of research—from business functions, such as administration and staffing, to study startup, clinical matters, and operations. They need support from a proper infrastructure and team within their practices and institutions, and from sponsors and contract research organizations (CROs) to alleviate the administrative burden of conducting clinical trials.

"Collectively, our industry is addressing this with solutions such as the TransCelerate Shared Investigator Platform with which we are currently working to get our sites registered," Sheller says.

To find the right PIs, Sheller's team has enhanced its collective knowledge of clinical trial activity (i.e., start-up, enrollment, data management) with a robust internal database coupled with a partnership with a large central institutional review board (IRB) consortium that offers a

comprehensive database of trial and site performance, representing 95% of all industry-sponsored protocols worldwide. That consortium keeps a massive data warehouse with data coming from more than 400 public domain data sources, plus the 25 companies under its own roof. With this capability, they consult with sponsors to help them work as quickly as possible to answer these two questions—does this drug work, and is it safe?

Sheller's group, which oversees more than 200 trials, including many oncology studies, as well as infectious disease, vaccines, and more, accesses both data sources to help identify the PIs and sites with the right infrastructure and metrics to support the likelihood of their reaching enrollment targets within timelines and conducting top-quality clinical research. According to Suzanne Caruso, vice president of clinical solutions at WIRB-Copernicus Group (WCG), "This approach is possible because we have data on how quickly investigators are able to enroll patients, based on how many trials they have completed in specific therapeutic areas, and how many they have ongoing. These are two major indicators as to whether a specific investigator will be able to enroll. The goal is to reach 'last patient/last visit' as quickly as possible."

In a competitive market for the best sites, this approach is a win-win situation for Merck and for PIs with the right stuff, who are benefiting from filling their pipeline with studies, thereby boosting their chances for site sustainability, and possibly creating an environment for greater PI retention.

To continue in this direction, Merck has launched several initiatives; one effort involves targeting fewer sites with proven performance to enroll more patients. This is a critical departure from what is happening across the industry, whereby many sponsors and CROs are hiring large numbers of sites, with the expectation that each will enroll only a small number of patients.

According to Sheller, "In some trials, this makes sense, but for most, it does not, and reflects that the majority of sites fail to reach their enrollment targets. Our team, however, is working toward investing resources in fewer sites with a supportive research infrastructure and access to patients, while making our start-up processes more efficient. Our goal is to drive greater productivity while maintaining the highest quality."

This is a meaningful approach, as PIs and sites tend to chafe at being asked to enroll just a handful of subjects while being expected to maintain a costly infrastructure that could support more patients (see Figure 2). Further, contracting to enroll more subjects and actually doing so allows the site to maintain an optimal research infrastructure and conduct even more trials. According to Sheller, in 2018, her region has targeted a reduction in the number of sites by approximately 30% as compared to 2017. This is being accomplished by focusing on increasing site partnerships and matching trials with sites having the appropriate patient population and infrastructure.

Figure 2: Fewer Patients Per Site Per Study Discourages PIs

Christine Senn, chief operations and implementation officer at IACT Health, mentions that over the past few years, the company has seen a sharp decline in the number of patients it is asked to enroll for studies. "In some studies, such as COPD, we used to recruit seven times the amount of patients we are asked to recruit now—from about 30 to 40 down to about five or six today," she says.

This chart shows the decline in the mean number of patients IACT Health has been asked to recruit per study.

Year	Number of Patients/Site (Mean)
2011	20.86
2012	17.22
2013	16.21
2014	11.04
2015	8.79
2016	9.59
2017	9.90
2018	7.67

Source: IACT Health 2018

To reduce administrative burden for PIs while accelerating study start-up, Merck has taken additional steps. Sheller's region has set a target for use of central IRB services to maximize efficiencies, especially at large institutions. "Our target is to secure [that] 70% of selected sites within a given trial will use a central IRB," she notes. Every few weeks, she receives a report as to where the sites are versus the target, and currently, the team is meeting this goal.

Merck also launched a Master Suite program in late 2017 to facilitate laborious documentation, budgeting, and contracting processes. This program entails using core negotiated documents, such as a master confidentiality agreement, master contract, consent form, and master fee schedule. To further minimize PI and site frustration, the company has instituted a central point of contact for select partner sites who are participating in multiple trials.

"Each site has a site account manager, who is an experienced operational point of contact dedicated to partnering with sites, which ensures we understand each other's infrastructures, processes, and needs," Sheller explains. "Sites know they have a dedicated operational expert at Merck whom they can call if they aren't sure how to navigate something. PIs and sites really appreciate this. With all of these changes, we can move a lot faster and reach patients sooner."

Taking Steps

At a time when the industry is wrestling with a range of issues meant to improve operational and clinical quality while accelerating study conduct, improving the longevity of PIs who are active in clinical trials ranks among the top challenges. This well-known problem is supported by data, but with a flurry of initiatives meant to retain and nurture investigators, it is possible that the pendulum will start to swing in a more positive direction.

To take the first steps, there is a basic need for infrastructure. Without a staff of qualified, trained personnel, it is nearly impossible for a PI to conduct quality clinical trials with any degree of efficiency and timeliness. Creating this infrastructure can start with developing the physician through a sub-PI program, whereby eventually, the physician can assume PI status—and this is where the challenge to retain PIs begins.

According to Morin, "PIs are retained by earning and keeping their trust, by engaging them in the process of study conduct, by the availability of content experts on staff, by compensating them for the time they spend out of the office to attend meetings and onsite training, and through profit sharing."

Further, it is critical to thank PIs for their vital work. The industry has long realized that patients must be thanked for their contributions to scientific research, whether it's in the form of gift cards, dinner vouchers, parking reimbursement, or birthday cards. Similarly, physicians should be thanked as they forge ahead in the development of much-needed therapies.

With this mix of strategies and the broad-based initiatives described earlier, time will tell if the experts behind these efforts will make the desired impact to engage and retain PIs—one of the industry's most enduring challenges.

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CLIN OPS INSIGHTS

Industry Taking Action to Unify Clinical Operations

Jim Reilly, MBA

New life sciences industry research reveals there has been significant momentum toward streamlining clinical systems and processes over the past year. More than 300 clinical operations professionals from around the globe were surveyed for the Veeva 2018 Unified Clinical Operations Survey, which annually tracks the industry's progress in improving clinical operations. Nearly all (99%) clinical leaders recognize the need to unify their clinical operating environments, and most (87%) have plans in place to get there. Here's what we learned.

Need for Better Visibility and Faster Trial Execution

The widespread move to unify clinical environments is being driven by application and process silos that have resulted from the steady adoption of function-specific clinical technologies over the past decade. Standalone e-clinical applications, including those designed for electronic data capture (EDC), electronic trial master files (eTMFs), randomization and trial supply management (RTSM), and clinical trial management systems (CTMSs), are now the norm. Further, newer, purpose-built applications for purposes such as study start-up are gaining traction.{1}

Faced with a landscape of disparate systems and processes, more than three-quarters (77%) of those surveyed find better visibility across their clinical trial processes a top driver for unifying clinical applications. Other primary drivers include faster study execution (67%), improved study quality (62%), and increased productivity (51%) (see Figure 1).

Figure 1: Top Drivers for Unified Clinical Operations

On average, companies use four applications to manage their clinical studies, and more than one-third (38%) use at least five applications. While such applications have been critical to modernizing clinical processes in key areas, they have also created common operational challenges with application and system silos. Integrating multiple applications (74%) is the top challenge reported by both sponsors and contract research organizations (CROs), followed by reporting across multiple applications (57%) and managing content and data across them (56%).

However, the survey shows that organizations extensively using standardized operational metrics and key performance indicators (KPIs) to measure trial performance have fewer challenges than their peers across key trial processes, most notably study performance metrics and reporting (44% versus 66%, respectively), as well as visibility into TMF status (32% versus 45%, respectively). In addition, organizations using metrics are four times more likely to have programs in place to unify their clinical applications than those not using metrics (47% versus 12%, respectively).

Increased Shift to eTMF Applications to Optimize TMF Processes

With the focus to improve clinical operations, companies are looking for more advanced, purpose-built systems to impact visibility, collaboration, and compliance. The survey reveals that adoption of eTMF has grown significantly, and it is now the second-most commonly used clinical system at 66%. In fact, the number of organizations now using eTMF applications has quadrupled since 2014, with 50% of sponsors using purpose-built eTMF applications, versus 13% in 2014 and 31% in 2017.

This increase is matched by a sharp decline in the use of content management systems and file shares. This signals a shift away from general-purpose methods—typically used in "passive" TMFs—toward a mature, active TMF operating model in which TMF processes and information are managed in real time. These active TMF solutions have a positive impact on inspection readiness and trial performance. Automated document exchange and tracking replace iterative, paper-based processes, study progress is made visible to all stakeholders, and centralized oversight and use of metrics enable a constant state of inspection readiness.{2}

This new model, and the emergence of modern systems to support it, are helping to drive change in the industry. Sponsors and CROs are now looking to optimize TMF processes in order to improve inspection readiness (70%), visibility (61%), and automated tracking and reporting (57%).

Streamlining Study Start-Up Now a Major Priority

Organizations are also looking at upstream processes as an area of significant potential, focusing on study start-up and leveraging study start-up applications as major priorities. It is estimated that 70% of studies run more than one month behind schedule, costing sponsors between $600,000 and $8 million per day of delay.{3} With as many as 11% of sites failing to enroll a single patient, and another 37% failing to meet enrollment targets, poor site selection can increase the cost of trials by at least 20%.{4}

Consequently, 83% of organizations say they have initiatives under way, or will within the next year or so, to improve study start-up processes. Top drivers for improving study start-up include faster study start-up times (63%), improved site feasibility and site selection outcomes (48%), and better visibility into site performance (44%).

Opportunity to Improve Clinical Trial Performance with CTMS

With the amendments in 2016 to International Council for Harmonization E6(R2) Good Clinical Practice guidelines, companies are now required to document the rationales for their chosen trial strategies, including the use of systems and processes.{5} This may have contributed to survey respondents' desire to improve the use of CTMS in their trial operations.

Nearly all respondents (99%) have challenges with core trial management processes, such as study performance metrics and reporting (51%), study and site management (49%), and resource management (45%). The majority (84%) also report significant deficiencies with their current CTMS applications; most have applications that cannot fully support a range of key functions, including governance and oversight (89%), resource management (88%), and issue and task management (86%). They see improving the CTMS as a way to gain greater visibility (70%), more proactive risk identification and mitigation (65%), and improved study analytics and reporting (61%).

Key Findings of *Veeva 2018 Unified Clinical Operations Survey*

- Nearly all (99%) respondents report the need to unify clinical operations, and 87% say their organizations have, or plan to have, initiatives in place to do so.
- All respondents say they want to improve the use of CTMS in study operations. Drivers are greater visibility (70%), more proactive risk mitigation (65%), and better study analytics and reporting (61%).
- Organizations have made progress in modernizing trial processes with purpose-built applications such as eTMF, ensuring a constant state of inspection readiness (70%), increased visibility and oversight (61%), and improved collaboration (42%).
- Consistent with the aim to improve study execution, study start-up is a priority focus. Most (83%) organizations have programs to speed study start-up (63%), streamline contract approval cycles (48%), and improve site selection (44%).
- Organizations that use metrics (77%) report fewer challenges with clinical operations, and are four times more likely to have programs in place to unify their clinical applications than those not using metrics.
- Those that have programs in place to unify their clinical landscapes are also more likely to use operational metrics to measure performance, manage risk, and implement process improvements.

Industry Moving Toward Unified Clinical Landscape

There is universal recognition of the importance of a unified clinical landscape in improving trial performance, and most companies are now working toward this goal. The industry sees a significant opportunity to run more efficient and effective trials by increasing visibility, quality, and speed of execution.

The majority of challenges faced by sponsors today in managing clinical trials still stem from the siloed nature of processes and applications, which makes visibility across the end-to-end trial life cycle difficult. Adoption of newer, more advanced, cloud-based applications is already having a measurable impact on visibility, collaboration, and compliance. Rationalizing systems, eliminating silos and manual processes, and having best-in-class applications on a single clinical platform are now critical steps toward unifying clinical operations.

With the growing complexity of trials and the ongoing need to improve compliance and leverage insight across the full trial life cycle in order to accelerate time to market, the industry sees unifying clinical environments as key to transforming operations – and major change is well under way.

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ICH IN FOCUS

Further Processing of Personal Data in Clinical Research

Madeleine Kennedy

While informed consent is a prerequisite for the enrollment of subjects in a clinical trial (according to the tenets of the International Council for Harmonization [ICH] Guideline for Good Clinical Practice E6(R2) 4.8), the General Data Protection Regulation (GDPR)* imposes a number of additional obligations on organizations that process personal data where "personal data" are defined as "any information relating to an identified or identifiable natural person ('data subject')" (Article 4(1)); and "processing" is defined as "any operation or set of operations that is performed on personal data or on sets of personal data" (Article 4(2)). However, the Regulation also allows for exemptions when personal data are processed for scientific research purposes. These exemptions pertain to the further processing of personal data for purposes other than the originally specified purpose (Article 5(1b)), the retention of personal data (Article 5(1e)), and the rights of data subjects (Articles 14(5b), 17(3d), 21(6), and 89(2)).

This column will focus on the topic of further processing of personal data, and will demonstrate that the exemption on such processing applies only under certain conditions and only if appropriate safeguards are in place. This article will also address the risks associated with personal data processing that is performed outside the boundaries of the controller's instructions.

* The GDPR applies to the processing of personal data by a controller or processor in the European Union (EU), regardless of whether the processing occurs in the Union. It also applies to the processing of personal data of data subjects located in the EU by controllers and processors not established in the Union if the processing relates to either the offering of goods or services to those subjects or the monitoring of their behavior where it takes place in the Union (Article 3).

Exemption on Further Processing

GDPR defines the "controller" as the party that "determines the purposes and means of the processing of personal data" (Article 4(7)). In clinical research, the sponsor is typically acting as the controller. The GDPR principle on "purpose limitation" states that personal data must be processed "for specified, explicit, and legitimate purposes and not further processed in a manner that is incompatible with these purposes" (Article 6(1b)). However, this principle contains an exemption, namely that further processing for scientific research purposes is not considered to be incompatible with the initial purposes (Article 6(1b)).

Article 89(1) clarifies that this exemption applies only if appropriate organizational and technical measures, based on a risk assessment, are in place to protect the rights and freedoms of data subjects. Article 32(1) lists the following safeguards to consider:

a) The pseudonymization and encryption of personal data.
b) The ability to ensure the ongoing confidentiality, integrity, availability, and resilience of processing systems and services.
c) The ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident.
d) A process for regularly testing, assessing, and evaluating the effectiveness of technical and organizational measures for ensuring the security of the processing.

Does this mean that sponsors can further process personal data (e.g., carry out additional secondary research) as long as they have appropriate organizational and technical measures in place? Not necessarily. GDPR provides context on what a controller needs to consider before processing the personal data for an additional purpose where the processing is not based on the data subject's consent, namely:

a) Any link between the purposes for which the personal data have been collected and the purposes of the intended further processing.
b) The context in which the personal data have been collected, in particular regarding the relationship between data subjects and the controller.

c) The nature of the personal data, in particular whether special categories of personal data are processed.
d) The possible consequences of the intended further processing for data subjects.
e) The existence of appropriate safeguards, which may include encryption or pseudonymization (Article 6(4)).

So if the further processing is not compatible with the first purpose, if particularly sensitive data are being processed and/or if data subjects do not have a reasonable expectation that their personal data may be processed for that additional purpose, particularly given the unequal relationship between research subjects and the investigator/sponsor, the interests and rights of the data subject could very well override the interest of the data controller (Article 47).

Further Processing Outside the Controller's Instructions

Now let's turn to the topic of further processing by a vendor. GDPR defines "processor" as the party that "processes personal data on behalf of the controller" (Article 4(8)). One might then assume that in clinical research, where a sponsor delegates trial-related responsibilities to a vendor, the vendor is the processor. However, it is not as simple as that.

GDPR emphasizes and reemphasizes that the processor may process the personal data "only on the controller's documented instructions" (Article 28 (3a)), and may not process them outside of those instructions, "unless required to do so by Union or Member State law" (Article 29). What this means is that if a vendor processes the personal data outside the controller's instructions, the vendor becomes the controller for that processing.

This is a material change for a vendor that has been contracted to take on the role of processor, because the controller's responsibilities are significantly more extensive than those of the processor. Furthermore, infringements of GDPR provisions carry hefty administrative fines of "up to 20,000,000 EUR or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher" (Article 83(5)).

The processor's responsibilities are limited to putting in place appropriate organizational and technical measures to support the controller in meeting its obligations. These include notification

and communication of personal data breaches and enabling subject rights. In addition, processors must only subcontract with additional processors with prior specific or general authorization that imposes the same data protection obligations on those subcontractors as those between the controller and initial processor, with the liability for any non-performance of those processors falling on the initial processor (Article 28).

The controller, on the other hand, is responsible for, and must be able to demonstrate, compliance with:

- Adherence with the personal data processing principles of lawfulness, fairness and transparency, purpose limitation, data minimization, accuracy, storage limitation, integrity, and confidentiality (Articles 5 through 11).
- Facilitating the exercise of data subject rights (Articles 12 to 23).
- Implementing data protection by design and default (Article 25).
- Implementing "appropriate technical and organizational measures to ensure a level of security appropriate to the risk" (Article 32).
- Using "only processors providing sufficient guarantees to implement appropriate technical and organizational measures in such a manner that processing will meet the requirements of this Regulation and ensure the protection of the rights of the data subject" (Article 28(1)).
- Notification to supervisory authorities and communication to the data subjects of personal data breaches if these meet the required thresholds (Articles 33 and 34).
- Conducting data protection impact assessments per the conditions outlined in Article 35 and consulting "the supervisory authority prior to processing where a data protection impact assessment…indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk" (Article 36).

It is important to note that while a vendor delegated by a sponsor to "perform one or more of a sponsor's trial-related duties and functions" (ICH 1.20) is contracted to act as the processor, the vendor is the controller where the vendor determines the purposes and means of the processing (e.g., in the vendor's processing of employees' personal data in the specific employment

context). In other words, the vendor wears two hats, depending on the type of processing performed.

If a vendor did process personal data outside the sponsor's instructions, how would a supervisory authority determine whether the vendor is acting as the controller for that processing? The supervisory authority would likely first review the contract between the sponsor and the vendor, including the transfer of regulatory obligations to assess the sponsor's instructions. The supervisory authority would also likely consider other factual elements, such as the expertise of the controller versus the processor and the degree of control and oversight by the controller to determine the degree of independent judgment that the processor was able to exercise. It is therefore incumbent on vendors contracting with biopharmaceutical companies to be diligent about ensuring that the sponsor's instructions are clear, so as not to risk overstepping.

Conclusion

While GDPR has created an exemption to the purpose limitation principle for scientific research, this only applies if appropriate organizational and technical measures are in place and the interests and rights of the data subject are not compromised. The regulation has also emphasized that further processing of personal data outside the boundaries of the controller's instructions carries significant liability risks for the party engaged in the further processing.

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SPECIAL ADVERTISING SUPPLEMENT

Competency-Based Training: Why Does It Matter?

Naila Ganatra, MEd, General Manager, Barnett International

What are competencies?

While the concept of competency development has been around for quite some time (R.H. White, 1959), it has increasingly come into focus in clinical research as clinical trials continue to become more complex. Competencies can be defined as a set of related skills, knowledge, and abilities that enable individuals to act in accordance with the prescribed performance requirements for their roles. Ultimately, these skills enable us to respond effectively to different situational inputs and issues encountered in our jobs.

By focusing on employee competencies, organizations can better align business goals and objectives and ensure that the appropriate employees are recruited and selected. Effectively, a focus on competencies (vs. only experience) provides employers with the opportunity to distinguish potential for superior job performance vs. average or below average results, and ultimately to better define and control performance in clinical research organizations.

Why are competencies especially important in clinical research?

Given the high stakes involved in clinical research, it has never been more important that the professional competency of all members of the research team is ensured. As an industry "we suffer from variances in how we identify, train, develop, and assess professional competency."{1} Several initiatives, including the Joint Task Force for Clinical Trial Competency,{2} ACRP's Core Competency Framework,{3} the work of the Multi-Regional Clinical Trials Center (MRCT),{4} as well as the work done by Furtado, Boggs, et al.,{5} have pointed to a lack of established standards in our industry, coupled with a critical shortage of qualified candidates for essential clinical research job roles. When we as an industry join together to focus on competency alignment with key clinical research role requirements, and

when we further support competency development for these roles and align them with harmonized standards, we will only benefit as a whole from these efforts, particularly given the regular movement of personnel within the industry.

How can competency development be best addressed in training programs?

The good news is that competency-based training can save valuable employee time and scarce training dollars. The fundamental change in thinking that needs to occur when moving from content-based training to competency-based training is how we think about time. Too often, companies view employee development as time spent in training, as opposed to an emphasis on the learning that occurred. With a focus on what is learned and how it is applied, managers can get more value from training budgets. Critical factors to bear in mind are:

- Recognizing that employees learn and develop at different paces and time spent is only one component – by holding the learning outcome constant and letting time spent in training vary by learner, better results are achieved.
- Understanding that not one training course or platform is always the best fit for a given situation: consider course content and platform versatility to meet learners where they are (i.e., mentoring vs. webinars, vs. self-paced courses, vs. publications – you get the idea!). Provide flexibility in training options and encourage participation in course selection based on learners' identified needs and areas of interest.
- Remembering that the classroom is only one part of the equation when it comes to competency development – it takes more involvement, feedback, and goal setting.
- Measuring learning by developing clear and fair assessment metrics (and use them!). All too often, assessment results are not followed-up on, despite the wealth of information (and opportunity for development) they contain.
- Understanding that line manager involvement is essential: set clear objectives and stick to them. Establish goals and hold employees accountable to their personal development.
- Rewarding personnel for being committed to their personal development, which is often taken on without a release from job responsibilities. Praise, promote, and reward as they achieve their goals.
- Providing opportunities for high achievers to lead; this helps others to model exemplary behavior and performance.

Other critical factors to consider in a competency-based training approach include:

- The need for clearly defined employee training procedures and objectives
- Availability of robust job descriptions (including experience, knowledge, skills, and abilities)
- Clear identification of job duties, functions, topics for "on-the-job" training
- Comprehensive training plans/options for learning and professional development (including on-the-job training)
- Selection of qualified trainers who are aligned with the defined requirements (competencies, work performance review)
- Ongoing maintenance of employee training files

And importantly, strategic training program design including the clear definition of learning outcomes, training platform considerations that are in alignment with the learning outcomes, and identification of "what's next" after training completion.

How Can Barnett International Help?

Barnett offers a number of role-based training programs designed for core competency development. Starting with learning outcomes in mind, the "Barnett difference" includes an emphasis on flexibility in training resources through the use of multiple platforms and learning technologies, coupled with deep subject matter experience and hands-on expertise in the roles for which we train. Our approach enables us to meet learners where they are, particularly in terms of their content requirements, availability, and desired learning outcomes. Barnett's training consulting experience further provides clients with training strategy development, focused specifically on performance development outcomes.

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