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The Authority in Ethical, Responsible Clinical Research

November 2020 (Volume 34, Issue 9)

Career Advice from Research Veterans

Clinical Researcher™

Association of Clinical Research Professionals

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EXECUTIVE DIRECTOR'S MESSAGE

Harnessing the Workforce the Public Deserves

Jim Kremidas

This month's issue of *Clinical Researcher* focuses on one of my favorite topics: the clinical trial workforce. You, the members of ACRP, are the foundation for vital work promoting health and prolonging life. The COVID-19 pandemic has more than merely reinforced the valuable contributions you make to advancing medicine and healthcare for all—it has changed many of your processes, perceptions, and expectations for increasing the efficiency and effectiveness of trials, perhaps forever.

ACRP members are big believers in paying it forward and paying it back. You'll see some great examples of that in two special features in this month's issue—"Career Advice from Research Veterans, Part 1: Focusing on the Fundamentals" and "Career Advice from Research Veterans, Part 2: Finding Meaning in the Mission." Both include invaluable insights and advice from successful thought leaders in our industry, including from the ranks of ACRP's Association Board of Trustees and the ACRP Fellows.

ACRP and its membership are also dedicated to harnessing the energies of newcomers to the field and those to come in the next generation of researchers. We are raising the quality bar for clinical trials by, among other tactics, promoting good ideas and projects that advance workforce professionalism in our industry.

Last month, for example, we announced Merck & Co., FuseCR, and Medical University of South Carolina as finalists for the ACRP 2020 Innovation in Workforce Development Award. This annual award recognizes organizations that exemplify the spirit of creativity and innovation

through adaptation, improvement, or development of new processes or tools that result in workforce development quality.

Finalists will share their innovative approaches to workforce development on November 12 during a free live webinar. The winning organization will be selected by ACRP's Partners in Workforce Advancement Executive Steering Council and announced in mid-November.

The Partners in Workforce Advancement (PWA) initiative continues to add members at an exciting pace. Watch this space for some exciting announcements on that front. As you may already know, the PWA is a multi-stakeholder collaborative effort to grow and expand the diversity of the clinical research workforce, and to set and support standards for workforce competence.

Organizations aligned with ACRP's mission are working together to improve clinical trial quality and outcomes for patients by focusing where others have not—workforce planning, development, and assessment.

PWA members include sponsors, contract research organizations, investigator sites, academic institutions, regulatory agencies, and others across the entire clinical trial ecosystem. Input from these organizations is already helping to improve clinical trial operations today and tomorrow.

As always, thank you for the work you do and for supporting ACRP in its mission. I welcome your thoughts and comments.

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

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CHAIR'S MESSAGE

Put Some Muscle Where Your Mouth Is

Paul Evans, PhD

It is encouraging to see and hear how much attention has been devoted to promoting diversity in the clinical trial patient population and workforce by ACRP, the U.S. Food and Drug Administration, and others across the industry in recent months. You cannot even begin to fix a problem until you identify it. Addressing a challenge of this magnitude requires rigorous self-examination, determination, and an openness to trying new ideas.

As we all know, clinical trials have a decidedly mixed history when it comes to interactions with minority communities. Tuskegee. Henrietta Lacks. These and other examples of gross misconduct and moral bankruptcy have damaged the view of clinical trials with many minority populations. It is a legacy we must confront, even as we find ways to reassure potential patients that these violations of basic human decency, not to mention good science, will not be tolerated again.

However, ACRP and others must now take the next step forward if we want to be true to our mission to advance the development of the clinical trial workforce. If talk and good intentions are the skeleton, meaningful actions are the muscle that will translate into systemic, and frankly long overdue, change.

Part of our rigorous self-examination as an industry must begin with the fact that personnel at sites are overwhelmingly white and generally based in areas where more non-minorities live and work.

Of course, most site staff are not overtly prejudiced, but we all have unconscious biases which manifest in many ways and can deter minorities even when the white practitioner thought he or she was being positive and inclusive.

It's time for site leaders and others to take proactive steps to introduce more diversity in their own workforce if they want to recruit more minorities as patients.

I was heartened by a recent segment of ACRPtv focusing on promoting diversity in the clinical trial workforce and patient populations. In the segment, featuring Lori Abrams, Executive Director of Patient Advocacy and Diversity at WCG, and Steve Smith, President of Patient Advocacy at WCG, each offered innovative, action-oriented ideas that could help the clinical trial industry finally begin to make significant progress in its efforts to broaden the patient population.

Another recent ACRPtv segment focused on the exciting work of Danielle Coe, founder of a new organization called Black Women in Clinical Research. Coe and colleagues have already seen positive impacts from their efforts to reach out and network with a wider population.

I think we can all agree that the clinical trial industry will benefit from the inclusion of more minorities in its workforce and patient populations.

Now is the time to put some serious muscle behind that well-meaning talk.

Paul Evans, PhD, is President and CEO of Velocity Clinical Research, and Chair of the Association Board of Trustees for ACRP in 2020.

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PEER REVIEWED

A Perspective on the Current State of Clinical Research Education and Training

Joseph M. Bocchino, EdD; Joan Butler, EdD, MS; Beth Harper, MBA, BS (OT)

The following review of the literature addressing the current state of education within the clinical research profession was undertaken to ascertain directions in which the profession and its supporting educators may be moving in order to further develop clinical research workforce capacity. The in-depth review elucidated a number of key factors that impact clinical research education, including: a) defining who comprises the clinical research professional; b) the role of medical education in clinical research education and training; c) the focus on competency-based education in the profession; and d) the recent rise of the translational research paradigm and its impact on clinical research education. This article will discuss the first three factors and introduce questions for further study related to education and training in clinical research.

Background

Over the past four decades, the domain of clinical research has been defined by heavy emphasis on the development of therapeutic interventions through the use of clinical trials. In more recent years an emphasis on public health, including behavioral and epidemiologic studies, has emerged, broadening the common view of clinical research to embrace the full scope of the U.S. National Institutes of Health (NIH) definition of activities encompassed by the field.{1}

It is important to fully understand the current state of education and training in the clinical research profession, in order to more fully engage the direction of the future. This paper strives to provide a current state perspective. Our focus in this review is not to assess and describe the variety of programs and venues; instead, we will discuss the three key factors impacting clinical research education, as identified through our review of the literature.

Methodology

We conducted a review of more than 3,800 abstracts and articles in our initial search, the majority of which focused on specific clinical research studies and findings, rather than education and training. The review identified 76 articles and documents for further, in-depth study. Deeper analysis of the 76 articles and documents yielded four important considerations for informing the future direction of clinical research education and training, with the first three being addressed in this paper:

- Clinical research roles and identity
- Medical education and clinical research
- The role of competency-based education in clinical research
- The relationship between translational and clinical research

Clinical Research Profession: Roles and Identity

The clinical research profession has been characterized as an "umbrella" that incorporates a number of roles and subcomponents supporting an entire field of work.{2} Viewed through a different lens, clinical research represents a series of competencies, each spanning a continuum of varying levels of expertise necessary to fulfill the stated role of the position holder.

Within the workforce, the profession is often characterized as a series of position titles and job descriptions that tend to focus on specific clinical research domains{3} or professional disciplines.{4} Remarkably, we were not able to find a credible estimate of total employees engaged in clinical research globally. This fact underlies some of the challenges in defining the scope of the clinical research "profession."

The challenge for educators and trainers supporting the clinical research profession is to identify appropriate learning objectives{5} when the individuals making up its workforce range from scientifically trained clinicians and seasoned researchers to newly minted, inexperienced individuals just entering the profession. That being said, learning and training objectives have focused heavily on the responsibilities associated with monitoring trials on behalf of their sponsors, the protection of human subjects, and the tenets of Good Clinical Practice, as these domains apply in some manner to the largest populations of the "clinical research profession."{6}

Several relationships emerge in the literature that are characterized by distinct professional credentials and clinical research roles. For example, the relationship between the nursing profession and the role of clinical research coordinator (CRC) is well recognized across study sites and sponsors.{7} In a similar fashion, medical doctors distinctly fulfill the role of principal investigator (PI) more often than not.

Beyond the most well-known roles of the field, defining who the clinical research professional is—as well as the full scope of those who make up the profession—takes on more complexity. Nevertheless, it is easy to understand how both the medical education literature, which we will discuss in the next section, and the nursing education literature influence the education and professional development of "clinical researchers" from these two health disciplines. The education tradition of each discipline influences what elements of clinical research training are emphasized within each profession.

Recently, other disciplines such as biostatistics and data management have become more evident in their influence on the clinical research profession. Historically viewed as auxiliary within clinical research, both biostatistics and data management have emerged as equally significant as more commonly recognized contributors in terms of their overall impact on the successful conduct of clinical research. As clinical research emerges as a more interdisciplinary profession, these two disciplines further expand the breadth of expertise recognized within the profession. {8–10}

However, key questions arise that are not clarified by the literature, including:

- What relative priority do incumbents engaged in clinical research place on their original field of study (e.g., medicine, nursing, biostatistics, etc.) when compared to their assigned roles in the conduct of clinical research (e.g., PI, CRC, or statistician as examples)?
- What role does the practice of clinical research play in the assumption of professional identity by those engaged in this work? (Education and training typically have served a primary purpose in developing identity across the professions.){7,11}
- How does interdisciplinary work like clinical research impact professional identity in the traditional health related professions?

A closer look at medical education and its impact on clinical research training provides some insight on these questions.

Medical Education: Impact on Clinical Research Training

Lurie{12} points out that up until the past 15 years, medical education relied heavily on written test outcomes to measure physician competence. However, a wide variation still exists across educational institutions of what constitutes competence in medical education.{13}

Carraccio et al.{14} describe a 21st century "Flexnarian revolution" necessary to move medical education from a then "current structure and process-based curriculum" to one that is competency based." As such, over the past 20 years medical education moved to adopt a more competency-based educational model. For example, in 1999, the Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS) jointly agreed upon six competencies for the certification and maintenance of certification of physicians.{15}

The ACGME/ABMS move specifically targeted graduate medical education and generated a major shift in medical education and training over the next 10 years, as elucidated by Frank in a 2010 systematic review of the literature.{13} That review also revealed widespread heterogeneity in characterizing the variation in medical education programs across the country.

Albanese et al.{15} undertook an effort to define competency for medical education, pointing out that variation was global and that it was unclear whether the differences were semantic or substantive.

In the same time period, Cook et al.{16} specifically called for competency-based education and standards to address issues of patient safety and accountability on the part of medical professionals in service to the general public. Lurie{12} elucidates a number of shortcomings associated with competency-based medical education, among them the absence of humanistic attributes and the lack of assessment tools for higher order skills like critical thinking and judgment. Gunderman et al.{17} describe learner perspectives that interpret competency-based medical education as a mechanism for ensuring a minimum required level of competence, as opposed to maximizing individual higher potential. Gonsalves and Zaidi{11} report on a study in which medical trainees describe the negative impact of competency-based education on "professionalism," as the trainees interpret directors' emphasis on step scores as overriding trainee professionalism, a reminder of Lurie's{12} claim of heavy reliance on test scores in medical education.

Clinical research training and education have developed in a similar manner into a competency-based discipline defined by a set of core areas of expertise.{18} It is not fully clear whether the emphasis on competency-based education in medicine drives the trend toward the same approach in clinical research. Quite possibly it was an Institute of Medicine report from 2002, which called for all health professions to adopt a core set of competencies,{19} which led to this progression. What is clear, though, is that the health professions in general have all adopted a competency-based educational approach and continue to refine it.{20,21}

Much of the current clinical research education in medical schools is now focused on translational research. Despite this shift in academic medical research, it is noteworthy that the recently issued "core Entrustable Professional Activities" by the Association of American Medical Colleges, defining 13 required activities that all medical students be able to perform upon entering residency, makes no mention of clinical research. This makes sense, given the primary focus of medical education at the undergraduate level.

However, at the graduate level, ACGME common program requirements state that curricula must advance a resident's knowledge of the basic principles of research, including "how research is conducted, evaluated, explained to patients, and applied to patient care." The program requirements leave to each medical discipline the approach and specifics of what content is to be taught, resulting in much variation even within disciplines, as evidenced in a review of 38 hematology/oncology fellowship programs by Safa and Jazieh.{22} Rangan et al.{23} calls for standardization of research training for all specialty medical trainees, to address broad variation across 62 medical specialty research curricula analyzed.

Competency-Based Education in Clinical Research

Competency-based education is described in detail by del Bueno,{24} and may be synthesized as the educational focus on predetermined outcomes or "competencies" along with an evaluation method. Outcomes are stressed over process; however, as del Bueno points out, it may not be one over the other. Since 1978, education within the health professions has focused heavily on competencies, as we can see within the clinical research profession. Overall, we can say that we do not have reliable research that documents clearly the effects of outcome or competency-based clinical education.{25,26} Within clinical research we continue to strive for relevant standards and metrics for assessment.

Sonstein et al.{27} point out that clinical research has progressed over the past two decades from a regulatory compliance–driven activity to one focused on competency. They go on to point out that even the global standards that guide training for clinical research are, at best, vague. Early on, professional organizations like Association of Clinical Research Professionals (ACRP) and the Regulatory Affairs Professionals Society (RAPS) began developing and have listed competencies associated with various clinical research roles. More recently, a consortium of clinical and translational research centers has developed and published through the National Center for Advancing Translational Sciences (NCATS, part of NIH) a set of core competencies for translational researchers which includes traditional components of clinical research.

Of importance for this discussion, representatives from a broad-based assembly of constituencies in clinical and translational research came together in 2013 as the Joint Task Force for Clinical

Trial Competency, in an effort to harmonize core competencies for clinical research professionals. Kohara et al.{28} chronicle the development of competencies attributed specifically to the role of CRCs. While quite extensive, the list was derived from a review of presentations and interviews conducted with thought leaders in the field of clinical research.

This raises a question as to who determines "needed competencies" and for which domains. Furthermore, we are compelled to ask how we integrate competencies across professional roles like the CRC, the clinical research associate, or the PI to ensure that we are able to address the overall goals of clinical research through the designated workforce.{29}

In this regard, Sonstein et al.{2} through a review of self-assessments elucidate the need to differentiate between "competency" and "proficiency" as we think about expertise in clinical research. The implication of this differentiation is to recognize that a purely competency-based training and educational model may not achieve the overall goals needed for a proficient clinical research workforce.

Morcke, Dornan, and Eicke{25} point out that the progression of outcomes-based education, heavily linked to contemporary competency-based approaches, was heavily criticized in the 1970s for reducing focus and development of skills associated with values, judgment, and insight. Lurie{12} discusses the humanistic shortcomings that may emerge from a purely competency-based education model. Taken together, these researchers may ultimately be facilitating a broader move to a more blended approach to developing the clinical research workforce by integrating outcomes and competency.

It is important to note for all reading this paper that the literature supports all the efforts put forth to identify and differentiate competencies in clinical research; the question raised here is whether we have gaps in our training and education that can't be met through competency-based education. As an example, Alsumidaie{30} describes findings that do not correlate experience with performance outcomes in clinical research, and furthermore raises questions about the relevance of surrogates or benchmarks for assessing competence in certain areas of clinical research.

Hartl et al.{31}, looking at how a specific medical education program utilized longitudinal blocks to develop competence, elucidate the complexity associated with thinking of the temporal nature of experience and automatically linking it to acquisition of competence or expertise.{32} Calvin-Naylor et al.{33}, as many other authors also do, describe in detail the process for identifying and developing domains and associated assessments, but does not elucidate the "thinking" behind the selection of such choices.

Dauphinee et al.{34} question directly whether we can validly assess competence in medicine, raising that same specter for our discussions of clinical research. Finally, Hodges and Akroyd{35} illustrate the lack of connection between PI certification and actual performance outcomes, as measured through reported site deviations. These examples suggest that we have gaps in our understanding of, and capacity to, leverage competency-based education fully to achieve our workforce development goals within clinical research and that this will require further exploration.

Finally, a critical consideration for our understanding of competency-based education in clinical research is to recognize the emergent nature of requirements to conduct clinical research. Innovation and technological advancements are redefining roles{5}; as such, competency may be evolving as a "situational" construct depending on the nature of the workplace, the specific requirements of specific sponsors, and/or the capabilities of their partners supporting the clinical research efforts. In this vein, Sargeant, Wong, and Campbell{36} delineate a wide range of considerations that may lead us to consider the intersections between competency-based education, continuing professional development, and even implementation science as pathways to addressing the educational needs of the future workforce.

Summary

We have developed a comprehensive understanding of the factors and dynamics that are influencing the direction of clinical research education. This paper was undertaken well before, and essentially completed prior to, the emergence of the coronavirus pandemic of 2020, which will undoubtedly influence education in the clinical research discipline. It is premature to

anticipate where this influence will lead. Our review clearly elucidates the changing nature of clinical research practice, how roles are defined, and how competencies define the field.

As a result, we have identified a number of discussion points that may help guide future inquiry on this subject:

- As more professional disciplines fall under the umbrella of clinical research, how will we leverage educational programs for those disciplines to integrate the core tenets of clinical research early in professional and academic training?
- The goal to be striven for is that clinical research education not be treated as an "add-on," and that it would help situate the individual's learning to recognize clinical research as part of his or her professional identity.
- We may need to move clinical research education "upstream" in the development of the health professions.
- How do we foster a truly interdisciplinary clinical research workforce?
- More work is necessary to fully explicate the relationships between stated clinical research competencies, actual job performance, and methods for assessing both to derive value for both employers and each clinical researcher.
- How will our currently stated clinical research competencies facilitate innovation and professional success within the field?
- We need to look more closely at the relationships between stated clinical research competence and the actual outputs and outcomes of clinical research activity.

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SPECIAL FEATURE

Three Ways Site-Centric Solutions Streamline Study Execution

Anna Argyris, MA, CCRP

It is an ongoing problem for the clinical research enterprise that the ever-growing layers of complexity involved in conducting clinical trials make it harder for sites to work efficiently and collaborate with sponsors and contract research organizations (CROs) across their studies. Research teams struggle to balance an increasing number of information requests from sponsors while providing high-quality care to study participants. Stakeholders in the industry are moving quickly to find better ways of working together, but the overreliance on paper-based processes makes study execution difficult.

Many sites today still capture information using paper, spreadsheets, or fragmented point solutions that weren't built for their operational needs. Research administrators use manual, time-consuming processes to fill in the blanks between information silos and systems that don't talk to each other.

To reduce administrative burden, investigative sites are shifting toward more digital, connected ways of working by adopting site-centric technology. These advanced solutions can standardize site operations, streamline information exchange, and improve research staff engagement to accelerate clinical research and deliver critical treatments to patients faster.

Standardize Processes Across Studies to Enable Paperless Trials

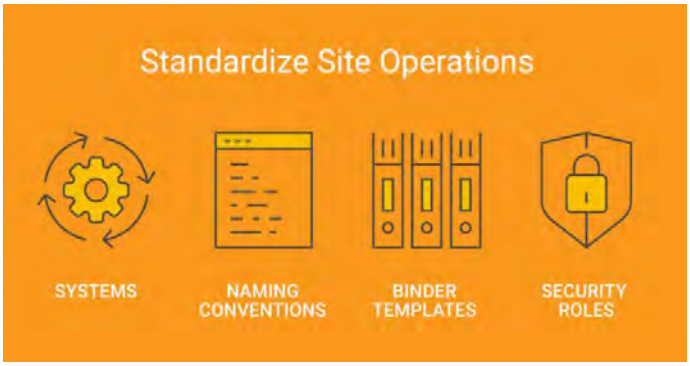
Solutions specifically built for sites help investigators standardize processes across studies to drive greater efficiency, improve compliance, and run paperless trials. Regulatory document management, for example, is a key area for modernization.

An eRegulatory system can replace paper binders and standardize how documents are stored and managed, increasing efficiency. With an eRegulatory system that can handle electronic signatures, document version control, certified copy workflows, and full text document search, sites can reduce the burden on research teams to scan and manually upload files to shared drives and across multiple sponsor portals.

Sites can also enable self-service access to regulatory documents for sponsors, freeing up research teams to focus on patients. Over time, sites can connect their eRegulatory solution to sponsor systems to simplify information exchange while ensuring secure, controlled access to their study information. Research sites are now rightfully accelerating the shift toward modern, site-centric solutions to streamline regulatory processes.

Site-centric solutions should include standard document naming conventions to identify content quickly, automatic document filing to eliminate the need of manually filing a document across multiple studies, and security roles and access levels to ensure the right people can get to the information they need (see Figure 1). These features simplify processes and maintain compliance, improving how trials are run.

Figure 1:



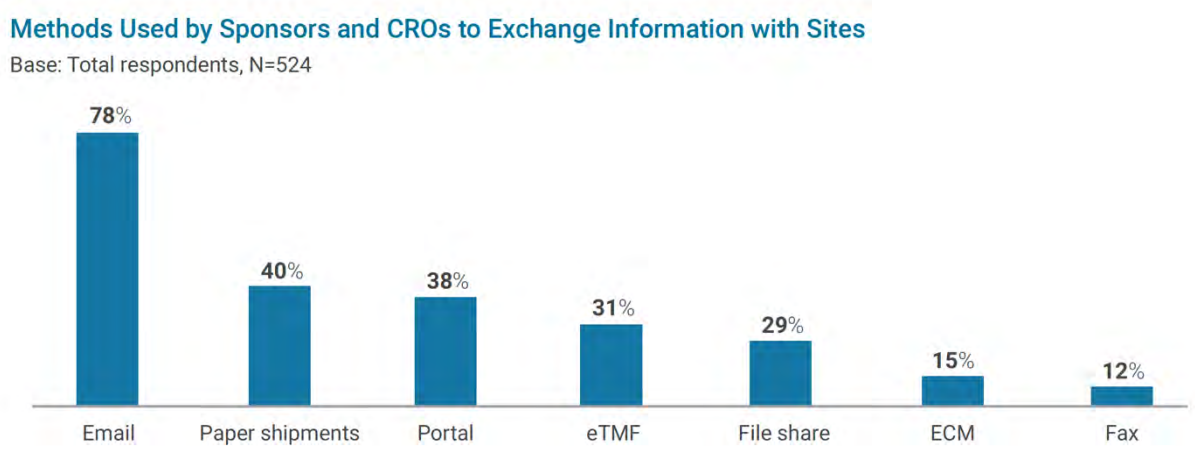
Standardizing site operations enables sites to measure quality and compliance across research and frees up study teams to focus on providing care and treating patients. It also can significantly improve how sponsors, CROs, and sites work together during trials, enabling a more transparent, paperless, and efficient way of managing studies.

Streamline Information Sharing Among CROs, Sponsors, and Sites

Sites generate a significant amount of paper documentation during a clinical trial that is incredibly difficult to share with sponsors and CROs. The original source, which is typically paper, combined with printing electronic medical records (EMRs) and wet-ink signatures, often leads to manual and paper-based information exchange.

According to the 2020 Unified Clinical Operations Survey Report,{1} e-mail (78%), paper shipments (40%), and portals (38%) were still found to be the predominant way sponsors and CROs exchange information with sites (see Figure 2). Unfortunately, these methods increase administrative effort, reduce efficiency, and lengthen the clinical trial process. Nearly all respondents report significant challenges with the methods used to exchange information with sites.

Figure 2:



Many sites still print records for their study monitors, adding complexity to information sharing in trials and keeping the site reliant on paper. When onsite monitor visits stopped during

COVID-19, many sites shifted to sharing documents via e-mail or fax or enabling direct access to their EMR system.

Adopting site-centric technology can resolve many of the existing issues with information exchange in clinical trials. One of the key enablers for better collaboration between sponsors and sites is a modern remote monitoring solution.

When sponsors and CROs have different study monitoring requirements, it can increase administrative work and process disparity for sites. By standardizing on one remote monitoring solution, sponsors, CROs, and sites can reduce time-consuming onsite visits, improve oversight, and remove logistical barriers that can slow study timelines.

Looking toward the future, remote monitoring will be an essential part—even a requirement—for clinical trials going forward. While remote monitoring provides clear benefits to sponsors and CROs by reducing travel costs and increasing utilization, research sites can easily standardize monitoring efforts to achieve efficiency gains that speed execution.

Site-centric solutions that enable investigators to standardize across studies ensure consistency, reduce training fatigue, and improve trial data quality. Sites can then spend more time with patients and less time preparing administrative requests. The result is streamlined information sharing across end-to-end processes for better collaboration and, ultimately, faster trials.

Improve Proficiency and Reduce Training Burden

Research teams express frustration from working with multiple disparate systems with different processes, logins, and training requirements.{2} To enable people to work smarter, sites are adopting site-centric solutions.

When systems are built to streamline and standardize site operations across studies, the burden of training is lowered. Trading multiple point solutions and manual processes for a single system that handles investigator site files and remote monitoring provides value by making it easier for staff to become more proficient.

Site-centric solutions reduce logistical challenges such as managing multiple logins and losing system access that can slow trials. Fewer systems and logins lead to fewer questions and access issues for study teams, allowing more time for high-value tasks like delivering care to patients. Having one site-owned system ensures that documents are safe and filed consistently across studies, despite turnover of research coordinators and clinical research associates.

Site leaders can also gain insights across trials that help them make better, more informed decisions. For example, if users can see how long it takes to collect signatures, they can focus efforts on improving turnaround times—and if they can see when documents are about to expire, they can do a better job on updates to improve compliance and operate more efficiently.

Creating a Go-Forward Plan

Investigators looking to build a resilient research infrastructure can start by evaluating software created specifically for sites by a technology partner who understands investigator pain points. Consider providers who are focused on site success, who are well known and trusted by sponsors and CROs, and who advocate for site needs. Taking these criteria into account helps speed the acceptance of new systems and positions sites for long-term success.

Once the site's leaders have decided to implement a site-centric solution, it is time to put together a plan. The following steps will help guide sites toward success:

- **Know what success looks like.** Evaluating new technology requires clear goals and outcomes, such as improved visibility, consistency, quality, and speed. Identify the key performance metrics that will be used to determine if these goals have been met.
- **Identify pain points and barriers to success.** Evaluate processes that are manual, time-consuming, error-prone, or not designed for your needs. For example, if unplanned downtime, paper-based processes, or variance across departments and studies are slowing trials down, determine more sustainable ways of working.
- **Focus on outcomes, not features.** When evaluating systems, start by determining the optimal outcomes and rank them in order of importance. With clear objectives in mind, research teams are less likely to be tempted by every "bell and whistle" a system can

offer, and can stay truly focused on the functionality that addresses the challenges the site is looking to overcome.

- **Evaluate the software provider, not just the software.** When evaluating vendors, look beyond their sales and messaging to understand their history, reputation, approach to building software, and proven customer success. Consider the vendor's ownership profile, financial stability, and development methods, and then speak with other customers about these factors. Consider a proven technology provider with a track record of innovation and success with sites and acceptance across the industry.

Conclusion

Sites that standardize operations, improve collaboration and information exchange, and make it easier for research teams to become proficient and streamline study execution will be positioning themselves for success in the clinical research enterprise going forward. With site-centric solutions, investigators can achieve higher levels of standardization, efficiency, quality, and stakeholder engagement. If sites can run trials faster and more efficiently, the industry can accelerate the delivery of new drugs and treatments to the patients who need them.

References

1. Veeva Systems. 2020. Unified Clinical Operations Survey Report

2. XCRS. 2019. Impact Assessment of eClinical Technologies and Industry Initiatives on Sites

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