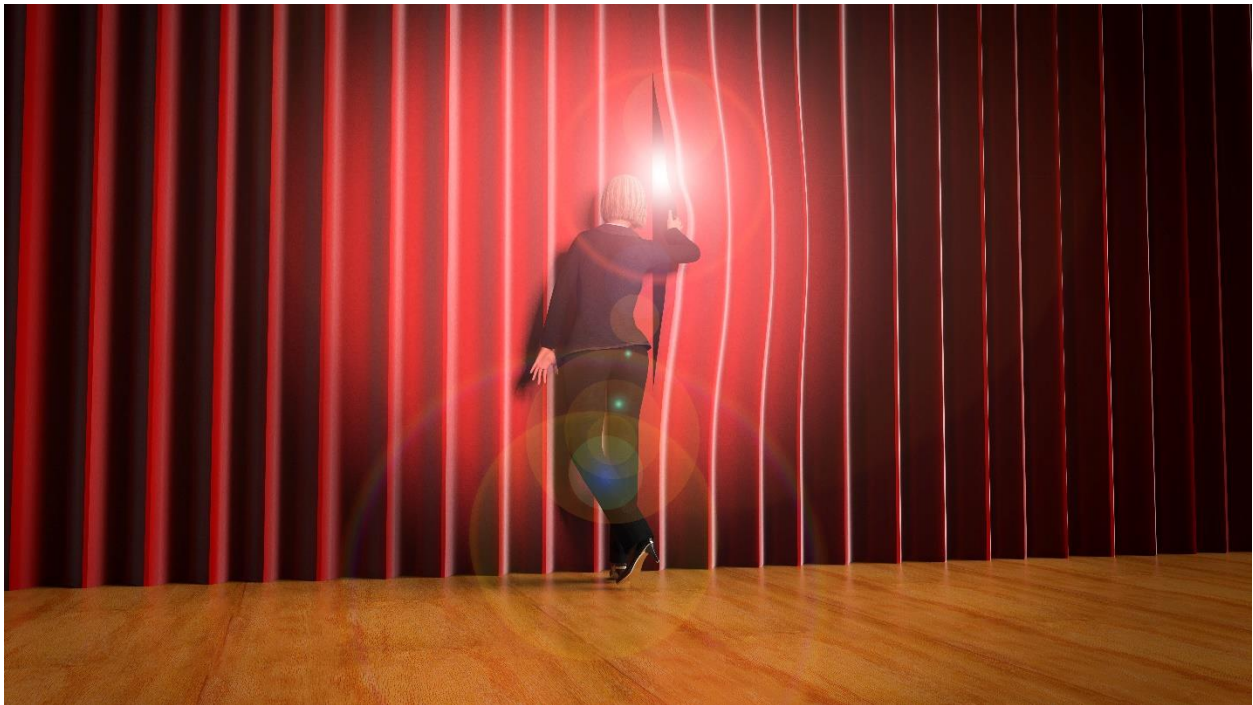# Clinical Researcher

**The Authority in Ethical, Responsible Clinical Research**

**May 2021 (Volume 35, Issue 4)**



**Careers and Challenges Behind the Clinical Trials Technology Curtain**

Clinical Researcher—May 2021 (Volume 35, Issue 4)

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EXECUTIVE DIRECTOR'S MESSAGE

# Let's Not Stop Here

Jim Kremidas

It's with decidedly mixed emotions that I begin this month's message—my final column as ACRP's Executive Director—at a time when so many exciting and inspiring things are happening in the world of clinical trials.

I'm so thankful I had the opportunity to support your efforts during my time at ACRP since coming on board in September 2015. As many of you know, I'm retiring at the end of May to spend more time with my family—especially my two grandchildren—but the leaving won't be easy.

Working with such talented people in this industry has been one of the most rewarding experiences of my professional life. Each day I went to work ready to marvel at what you accomplished, and some of your finest achievements have come since the COVID-19 global pandemic upended our world last year.

As of this writing, COVID-19 has taken more than 600,000 lives in the U.S. alone. However, those numbers would have been devastatingly higher if not for the incredible results the clinical research enterprise delivered in terms of developing safe, reliable vaccines in a matter of months. Even now, this truly historic achievement is being built upon in more labs and study sites so that new and improved treatments for COVID-19's full range of symptoms, long-term health complications, and emerging variants can come to market as soon as possible.

This is such an important industry, and you embody its spirit. Your work enhances and saves lives. A high calling, indeed.

Together, we've built a strong foundation for the clinical trials of today and tomorrow, but we can't stop reaching and growing now. We have momentum. We must use it to further advance the professionalization of the clinical trial workforce, increase diversity both in the patient population and among practitioners, and keep patients first and foremost in everything we do.

We also need clearly defined career paths and efficient ways to educate and welcome new entrants into this amazing career.

As you know, ACRP has been active in solo and shared efforts to define professional competencies, align those across the entire industry, and validate them through certifications.

Whether it's through the [Find Your Element Campaign](#), our new [Diversity Advisory Council](#), or the [Partners in Workforce Advancement](#), there are several tangible ways for you to harness your talents for the betterment of our industry by joining our efforts.

I'd like to close my final column by thanking you, the members of ACRP, for all you do. I'd also like to thank the excellent ACRP staff and members of our outstanding Association and Academy Boards of Trustees over the years for their tireless efforts to support our shared mission of promoting clinical trials designed to assuage suffering, improve the quality of life, and help people live longer, healthier lives.

My six years as ACRP's Executive Director have been a wonderful way to end my career. I cannot adequately express my appreciation to you for this opportunity.

The future for clinical trials looks exciting on so many levels. The trajectory is clear and upward. I will continue to admire all that you do and wish you all the best in the days ahead.

**Jim Kremidas** ([jkremidas@acrpnet.org](mailto:jkremidas@acrpnet.org)) is the outgoing Executive Director of ACRP.

CHAIR'S MESSAGE

# Changing of the Guard

Erika Stevens, MA

How will a change in ACRP's leadership impact the organization's strategic initiatives?

Under the direction of Jim Kremidas, ACRP rebranded; defined its value propositions for members, employers, and certificants; developed strategic alliances with complementary organizations; expanded certification offerings; engaged industry sponsors; and secured its foothold as the leader in workforce development for the clinical research enterprise. ACRP's strategic objectives rooted in the above include data-driven decision making, staff development, and training adoption.

Prior to Jim's leadership, ACRP lacked financial stability, required improved member services, and sat unrecognized by life science organizations. Today, ACRP stands with upgraded information technology infrastructure, streamlined processes, international alliances, data-driven reporting, and a visionary Partners in Workforce Advancement program. Still to come, ACRPtv will pass 100 episodes engaging industry leaders in thought-provoking discussions on regulatory issues, industry trends, patient perspectives, and diversity. Happening now, ACRP's fundraising efforts have kicked off in support of the Ride for Diversity as Sergio Armani, Association treasurer, and Rick Fisher plan a 334-mile bike ride in June to be followed by the launch of a major gifts campaign.

While leadership change may bring a new lens, the roadmap forged by Jim will be maintained. Meanwhile, if by chance you missed Jim's guitar performance in Nashville, we hope you will come to our next live ACRP conference in Orlando in 2022 to catch an encore.

I wish you all the best jusqu'a la prochaine fois (until the next time),

**Erika Stevens, MA,** is the 2021 Chair of the Association Board of Trustees for ACRP and leads Transformation Advisory Solutions for Recherche Transformation Rapide.

PEER REVIEWED

# The Pandemic Push to Virtual EHR Training and Optimization for Clinical Research

Paula Smailes, DNP, RN, CCRP

The use of computer systems to monitor and document research participant care is essential at academic medical centers (AMCs). Enhanced features of electronic health records (EHRs) can facilitate research workflows such as data mining, research recruitment, adverse event tracking, and research billing. While initially developed to be patient-centric, the role they serve with respect to research and discovery cannot be denied. Considering the vast amount of clinical data they collect, an important role of EHRs is how they identify whether new interventions in healthcare delivery lead to improved outcomes, along with health savings.{1} Further expanding on that point, it has been found that clinical trials conducted with EHRs may have increased generalizability, while requiring less time and money to conduct.{2}

However, while there are historically known challenges of EHR use for research,{3} no one imagined the challenges that a pandemic would bring. With the onset of COVID-19, researchers were forced into workflows for which we had not planned. While many workers were sent home in March 2020 to reduce exposure and increase safety, research operations at their institutions often needed to continue virtually. Research leaders around the world were forced to make quick decisions on how to continue to support the established research infrastructure. This became especially true with newly hired staff in the process of onboarding.

One essential onboarding need at any AMC is EHR training for researchers, followed by ongoing support through optimization. Training is the foundation for system use. This content delivery focuses on customization and efficiency, along with research workflows that can be accomplished by the system. Despite this critical role of this training, COVID-19 pushed institutions to determine how effective training for researchers could continue during a pandemic when physical distancing is a necessity. The following sections reflect lessons learned at the author's institution—a medical center based within one of the largest U.S. public universities.

**Training**

Before the pandemic, EHR training classes were held in a computer lab where new hires had their own computers and could actively engage in the system, while an instructor demonstrates workflows on a projected screen. This is known as instructor-led training. Less than one week after being forced into working from home, the first research EHR training class at our AMC needed to be taught. After considering a physically distanced, in-person approach vs. a remote, virtual training, the decision was made to go virtual.

Because we could not guarantee that onboarding researchers would have two monitors (one to observe virtual training and one to simultaneously follow along in the play environment), we needed to resort to a system demonstration. This placed more onus on the researcher to practice workflows in a "play" environment. By capitalizing on software such as Webex™ and Microsoft Teams, the remote training class could be conducted successfully. Using features such as screen sharing, chat, and hand raise, this format has the ability to be interactive similar to in-person training.

Aside from the method of delivery, no other changes were made. Session offerings continued to be every two weeks and available as self-enroll in our learning management system, or staff could enroll by phoning our training center. The content delivered did not change. Class sizes reached up to 20 attendees and were not capped, which was typical of in-person training. A total of 359 research attendees participated in two virtual training classes across 54 sessions taught during the first 12 months of virtual training.

*Benefits and Lessons Learned from Virtual Training*

There were several advantages to the virtual training. First, it offered end-user safety when they remotely joined the class from home. This also helped to ensure safety for training staff and eliminated travel time for commuting and parking, which can be costly. Minimal computer requirements existed for participants, but they did need to download software to view the training.

While there were benefits to virtual training, there were many lessons learned along the way. Prior to each virtual session, an e-mail message was sent to encourage users to attend from a quiet environment that was free from distractions. It also included electronic links to training materials and the phone number of the training center should there be a need for technical help. This is key, because there were instances when the attendee had computer issues and attempted to call and/or e-mail the instructor, who was otherwise teaching the class and not available to help.

In the first few weeks, the virtual classroom became overloaded due to demand on the system. It was necessary to reschedule one class due to technical difficulties. These issues were resolved quickly and did not persist over time.

A classroom etiquette also needed to be established. Many users wanted to keep their webcams on, but attendee behavior led to a request for all to turn them off. Examples of such behavior were trainees who were mobile or who had pets and children attending sessions. The absence of a webcam view eliminated distractions and made the demonstration the main focus of attention. For this same reason, a request was made for attendees to mute their lines to eliminate background noise, with the clarification that they could unmute and ask questions at any time.

*Evaluating In-Person vs. Virtual Training*

When the classes transitioned to virtual training, onboarding researchers were asked to complete the same post-class evaluation as those who attended the in-person training classes. Evaluations used a 5-point Likert scale, with 1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, and 5=Strongly Agree. The post-class evaluation was used as a quality improvement tool to provide feedback on the course content and instructor. This tool is standard for the multitude of EHR training classes taught at the organization. It became especially important to receive this feedback given the new format of instruction.

After six months of virtual training, an investigation was made as to how it compared to in-person training held during the six months prior to the pandemic shutdown. Using the mean scores of post-class evaluations, results showed that there was little difference in end-user satisfaction of both the instructor and class content (see Table 1). The learning management system is limited in terms of only providing the mean and number of respondents with the aggregate data, without information on data variability. Also, not all attendees completed an evaluation.

**Table 1: Clinical Research EHR Training Evaluations Pre- and Post-Pandemic**

| | Clinical Research Fundamentals | | Clinical Research Documentation | |
|---|---|---|---|---|
| **Metric** | 9/1/2019-3/13/2020 | 3/14/2020-10/15/2020 | 9/1/2019-3/13/2020 | 3/14/2020-10/15/2020 |
| **Instructor** | Mean (n=75) | Mean (n=64) | Mean (n=65) | Mean (n=47) |
| The instructor's teaching methods (slides, handouts, videos, etc.) were effective. | 4.4 | 4.5 | 4.4 | 4.5 |
| The instructor was able to provide me with clear examples. | 4.5 | 4.6 | 4.4 | 4.6 |
| The instructor demonstrated respect for my needs (questions/opinions) as a trainer. | 4.6 | 4.7 | 4.5 | 4.7 |
| The instructor's expertise/knowledge facilitated my learning | 4.6 | 4.7 | 4.5 | 4.7 |
| **Course Content** | | | | |
| The materials provided me with information that will help my job performance. | 4.4 | 4.6 | 4.4 | 4.5 |
| The practice exercises allowed me to practice new knowledge and skills. | 4.4 | 4.5 | 4.5 | 4.4 |
| I will be able to apply what I learned back on the job. | 4.5 | 4.5 | 4.3 | 4.4 |

*Qualitative Feedback*

In addition to quantitative results, the post-class evaluations offered researchers an opportunity to provide qualitative feedback. Recurring themes included:

- Provide directions for accessing the play environment prior to training. This allows for researchers to practice workflows prior to class and come prepared to ask questions.
- Provide a playground exercise as homework after class.
- Request for one-on-one sessions after initial training.

These suggestions for improvement were incorporated into the virtual training. The meeting appointment was enhanced to include detailed information for accessing the playground environment should users want exposure prior to the session. This information is also part of the post-training e-mail reminder encouraging attendees to review workflows.

Playground exercises are in development for specific research teams. Research leaders assist with content and scenarios.

Attendees are given the trainer's contact information to request one-on-one sessions at any time after training.

*eLearning Conversion*

Prior to the pandemic, EHR training for clinical researchers was slowly being converted to electronic learning (eLearning). This format exists as computer modules that are housed in our learning management system and done independently by the researcher at any time. Our initial research EHR class converted was a research scheduling class. Three weeks into the pandemic, the research billing EHR training conversion was complete and deployed for end-users. This became a great satisfier for research leadership to know that training could be completed conveniently for staff.

The remaining two classes—system basics for researchers and documentation—will be completed by the end of the calendar year 2021. The benefits of a training conversion from instructor-led to eLearning include increased learner satisfaction, substantial return on investment, and an ongoing means of refresher training. It allows learners to review information at their own pace from any location and at any time, whereas live, instructor-led training is limited in format by typically being done at a scheduled time in a computer lab where the instructor leads the class through workflows as attendees follow along on their own computers.

**Optimization**

Optimization refers to the process of ensuring that after training has occurred, EHR end-users optimally use the system. This could be in the form of personal customization, efficiency, satisfaction, and awareness of ongoing system changes and functionality updates.

*New Hire Follow-Up*

New hire follow-up from training was already established prior to the pandemic and continues in the same fashion, but virtually. The importance of this program is to allow researchers time to access the system and understand their responsibilities, then further assist in areas such as customization to their workflows and specific therapeutic areas, along with reporting. The goal is to improve researcher satisfaction and efficiency, but also to make them feel supported in their new roles as they transition into the organization. An EHR competency checklist is used to ensure that the newly hired researcher is using the basic system features taught in the EHR training class.

*Chart Audit Tool*

Approximately one month into the pandemic, a meeting with research leadership revealed an area of opportunity. Since many research studies were temporarily shut down, staff were working from home and in some cases, needed remote work to do. An EHR audit tool for research was developed. This tool was designed to be used for consented patients with EHR as a source document and serves as a quality improvement tool to ensure all records are audit-ready. Designed in Microsoft Excel, each study gets its own tab, with consented patients as columns and audit features as rows, which included metrics such as:

- Are visits within the study protocol window?
- Is a consent note documented?
- Has the investigator reviewed adverse events?
- Verify inclusion/exclusion criteria to ensure the patient qualified at the time of enrollment. Have any new events impacted eligibility?
- Are there any open notes that need to be signed?
- Has study drug accountability been documented?

A researcher self-assessment was included with the audit tool, so that individuals could not only audit charts, but their own EHR knowledge. If a researcher finds that he or she is not strong in some system features or has forgotten certain functionalities, a link to training materials in the tool points to the workflow for review.

*COVID-19 Research*

As studies restarted, researchers found themselves needing new workflows related to COVID-19 research and the EHR. Much of our organizational research is conducted on an outpatient basis, yet many COVID-19 studies were inpatient-specific. This led to researcher outreach and support for changes to their EHR usage habits. Issues of data privacy and security that arose were handled by leadership.

*Telehealth and eConsent*

For studies to continue, many clinical researchers turned to remote workflows and needed additional assistance with documentation efficiency related to telehealth practices. One group customized its flowsheet build to incorporate phone contact information, and this caused enough change in the original workflow to necessitate revised training documents.

Researchers also engaged in new ways of consenting; some chose to use the EHR to send research consents for review or utilized REDCap® for electronic consenting.

**Research End-User Support**

*Research Teams*

One consideration was the quarterly updates made to the system. While these occurred prior to COVID-19, the communication of changes afterward needed occur remotely. Turning to "super users" of the system, or designated EHR contacts within groups, allows for improved dissemination and a point of contact. These users meet monthly with the Principal Research EHR trainer to review emergent issues, recurrent themes, and educational tactics.

*Individuals*

Some areas also had multiple team members that needed individual support. Conducting one-on-one EHR support remotely isn't too different from doing so in person. Using screen-sharing software allows trainers to see an end-user's screen and instruct accordingly. This promotes work efficiency from both parties by eliminating travel time and conserving work time over the course of a day. As these optimization sessions are completed, they are tracked in a report and shared monthly with leadership.

**Conclusion**

The need for technology training continues despite the presence of a pandemic. In fact, the pandemic has provided opportunities to further engage in technology in ways not previously recognized and uncovered new and evolving needs that can be addressed with continuous, virtual EHR training and optimization.

As we have shown, capitalizing on virtual training resulted in little difference in mean evaluation scores vs. an in-person, instructor-led approach; however, the hope at our organization is to continue the training conversion to eLearning. When all is said and done, end-user support is just as crucial now as it was prior to the pandemic.

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SPECIAL FEATURE

# Overcoming Perceived Implementation Barriers to Decentralized Trials

Alison Holland



Decentralized clinical trials (DCTs) have existed for nearly two decades. However, DCTs, which incorporate advanced digital and remote technologies to conduct much of a trial at a patient's home, accelerated dramatically due to the COVID-19 pandemic. Global healthcare advancements could not afford to be stagnant, so sponsors and their partners shifted to this new model suddenly. The result was a 400% growth in DCTs that's expected to continue as more industry leaders recognize the economic, speed, and diversity benefits of this new model. In fact, 73% of sponsors and contract research organizations (CROs) say that they are currently using a hybrid decentralized model or plan to in the next two years.{1}

The randomized clinical trial model has needed an overhaul for decades, in part because of the lack of access to patients. Finding good candidates in the right locations, especially for rare disease trials, is difficult and contributes to 85% of trials failing to get enough patients enrolled. For patients who do enroll in a trial initially, an eye-popping half find it difficult to stay enrolled.{2}

Traditional trials have well-documented hurdles to patient enrollment and retention. Typically, 70% of participants live more than two hours from a trial site and face financially burdensome barriers, including transportation, missed work, or lack of childcare making it nearly impossible

to make site visits, sometimes multiple times a week.{3} These barriers exclude many low-income participants.

These long-standing challenges, coupled with the unique benefits of decentralized approaches, ensure the trend toward DCTs will continue well past the pandemic. Even so, perceived implementation barriers are causing some CROs, sponsors, and principal investigators (PIs) to remain cautious—potentially losing out on the leaps in efficiency, data quality, and patient enrollment and retention that DCTs afford. Here, we address the five most common obstacles, and how to overcome them.

**Change Management**

The life sciences industry has always been hesitant to change. With health at stake, everyone involved in a trial wants to be confident about how it is conducted. From CROs to PIs, the whole team must be on board to make a DCT successful. Education is key. Make sure everyone on the team is fully aware how decentralized aspects of the trial will help each team member do his or her job better, such as using eConsent tools to reduce or eliminate repetitive or manual data entry tasks. Digital tools in DCTs allow site clinicians to spend more time focused on the patient rather than paperwork.

Constant communication about expectations around process change and collaboration is also critical. Everyone involved in the trial process should expect to invest extra time up front to establish new ways of working together with the knowledge that it will save time in the long run. Disarm site teams about the misperception that DCTs will eliminate some long-standing research roles by clearly explaining how these roles will evolve, not go away. For example, with fewer manual workflows, researchers will be more efficient and can focus on more value-added activities and patient care.

"DCTs are not a one-size-fits-all solution, and every project should be assessed independently in the context of need, value, and return. This requires an experienced team," said Mike D'Ambrosio, vice president of real-world evidence and late-stage trials at Syneos Health.

For instance, D'Ambrosio noted that digital tools, artificial intelligence (AI), and machine learning platforms have been leveraged in support of COVID-19 vaccination trials to organize, analyze, and clean thousands of datapoints in less than 24 hours versus months if done manually. Sponsors and clinicians can leverage these decentralized tools to both improve data quality and optimize resource time, allowing them to work smarter and more efficiently, he added.

**Technology Adoption**

The perception that certain patients will not use or understand new technology is largely a myth. Researchers are finding that patients—including older generations—are more familiar with technology than credited, and eager to comply. The key is to decide what technology to use and then provide the right support and education.

In a recent decentralized study on macular degeneration—a disease that primarily impacts people over age 65—researchers found that age had no bearing on the use of remote technologies. The study, which needed to happen quickly and cost-effectively after being delayed for years, used digital technologies to screen 11,000 patients remotely for a rare genetic variant.

This trial would typically require more than 100 physical sites with patients living within a set radius of each and was forecast to cost upwards of $50 million. So, the sponsor took a decentralized approach to eliminate the need for physical sites. A single DCT platform was used to recruit, on-board, and oversee participants, slashing patients' time burdens in half. Patient enrollment, expected to take upwards of six months, took less than three weeks and the trial cost $20 million less than forecasted. Patient retention was near 100%, too, suggesting that remote technologies did not intimidate an older population.

Seniors have dramatically increased their technology use during the pandemic, using virtual tools for everything from booking virtual visits with their doctors to ordering their prescriptions online. Six in 10 seniors recently surveyed said they are embracing technology more than ever. In fact, telemedicine usage jumped 340% among Medicare-eligible seniors since the start of the pandemic.{4}

**Digital Immaturity**

The first fully virtual clinical trial was [Pfizer's groundbreaking DCT of 2011](#), which leveraged mobile phones to capture patient data and keep patients remotely in touch with sites across 10 states.{5} The U.S. Food and Drug Administration (FDA) hadn't quite caught up to advancing technology and solutions providers were still in the nascent stages of development.{6} Consequently, early DCTs lacked, tainting the model as a viable option long-term. Early negative experiences and the perception that technology still isn't ready have prevented some from investing in DCTs.

However, cloud innovations, the Internet of things,{7} and advanced mobile technologies provide a modern, reliable pathway for DCT implementation even as the industry is still evolving.

"Some people worry we are evolving too quickly—saying that we haven't figured out DCT version 1.0 yet and we are already at version 5.3," noted D'Ambrosio. "I don't think this is the case, but rather it demonstrates the critical requirement for robust change management. Technology is going to continue to evolve at light speed and with broadening utility. Rest assured, we will always adhere to strict compliance standards and test before roll-out. Each DCT project, site, patient, and protocol is unique. That is our challenge now—thoughtfully selecting and applying world-class solutions to meet all of the wider needs of the project stakeholders— not the technology per se."

To reduce potential technology issues, in some instances, it may be appropriate to have trial participants use their own device. Most importantly, DCTs should leverage a single platform with built-in flexibility to accommodate unique needs and changing requirements, sometimes mid-trial.

For example, in a recent hemophilia study, patients were recruited and onboarded through one DCT platform. They scheduled blood tests directly through the platform app. Once their blood was taken, the results went back through the same platform. Using a common platform allowed

PIs and doctors to easily collaborate and see the same data in real time, eliminating the silos with traditional trials.

**Data Consistency**

With patients dispersed and a mix of access to different technologies, another barrier is the potential for data inconsistencies. It's vital for teams to get consistent and comparable data, no matter where the patient is based. To do this, the same approach must be used with each participant, including when using a physical device to gather data. For instance, if patients are in China, Norway, and Ethiopia and will be given a consumer-grade wearable device to capture data, then each participant must be provided with the same device. Patients must also be taught how to use the device, to ensure the same data are collected from each participant in the same way.

"What is the purpose of the data collection? Is it exploratory data or data that will support an endpoint and must be regulatory grade? The key is to delineate between the two to determine the level of tolerance for variation on data collected from patients," explained D'Ambrosio. "With an [electronic patient-reported outcomes]–based clinical endpoint, for instance, standardization is critical because the data collected are directly tied to primary outcomes so there is much less tolerance for variation. Any DCT solution will need to leverage a robust, qualified system with a standardized way to capture data as well as a formal training program that teaches patients how to use that technology so patients can interpret questions in the same way."

It's critical to maintain a single data collection point and to provide patient participants with everything they need to use the technology correctly. DCTs must have a dedicated team with set processes to consult and make changes to data collection processes, when necessary, to ensure data consistency.

Additionally, DCTs should leverage the lowest common denominator technology for patients and be flexible about how data are collected. For example, in one DCT taking place across 43 countries, participants need to be informed in their language so they can properly consent to their data being used. However, all patients must consent using the same guidelines in the same way

for compliance. Technology allows the process to be standardized yet also accommodate each person, no matter their location or language.

**Compliance with Global Regulations**

Global DCTs demand a laser-like focus on local regulation compliance. For instance, eConsent processes may be governed differently in different geographic areas. However, global traditional trials also require compliance across continents. Recognizing the need for quicker adoption, the U.S. and European Union eased some restrictions to make DCTs easier to execute. In December 2020, the Decentralized Trials and Research Alliance (DTRA) was formed to advocate for more DCTs. Further, the FDA launched the Digital Health Center of Excellence in the fall of 2020, in part, to advance digital health technology used in DCTs.

The key to success in this area is to have a set person or team overseeing rules and regulations where each trial participant is based. The team must be proactive in its pursuit of global compliance. "There are concerns around scaled adoption of certain elements of a DCT such as eConsent due to ambiguity with different regulators in certain geographies. But there are data and learnings around adoption, retention, and other parameters that we can start to gather and then share the successes around eConsent in a vendor-agnostic way," said Dr. Craig Lipset, co-chair of DTRA.

With trials happening anywhere, DCT teams need to make data maps to understand before a trial starts how data will be used, where they will be gathered, and where they will ultimately go. Data mapping is vital to staying in compliance with data regulations, and it takes a team to stay on top of a data map. The trial sponsors must also be ready to modify the data map or change course as needed. Given the advancements of 2020 and clarified regulatory direction from the FDA and European Medicines Agency, complying with global data regulations is projected to get smoother as time goes on.

**The Next Phase of DCT Adoption**

For some organizations, DCTs still feel "all arms and legs," like teenagers experiencing a growth spurt. As more organizations become familiar with this model and recognize its positive impact, the industry will grow seamlessly into its new DCT physique.

Few things worthwhile are risk-free. DCTs allow patients anywhere in the world to participate in life-altering clinical trials by removing many access barriers for diverse participant pools. DCTs will transform healthcare but won't evolve without some growing pains. The key is to minimize risk where possible and maximize potential outcomes, working with experts to mitigate all perceived barriers to implementation.

"DCTs are fast-evolving and every day there is a new puzzle to unravel. There is a level of immaturity still and some unknowns, but the benefits far outweigh the extra effort to solve these complex problems," concluded D'Ambrosio.

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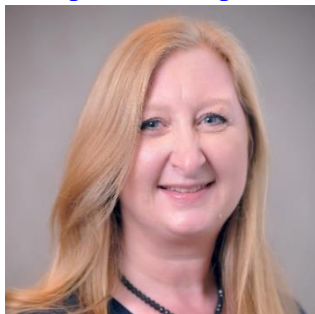
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CAREERS & CULTURES

## Tech Careers in Clinical Research

Alexis Gabard
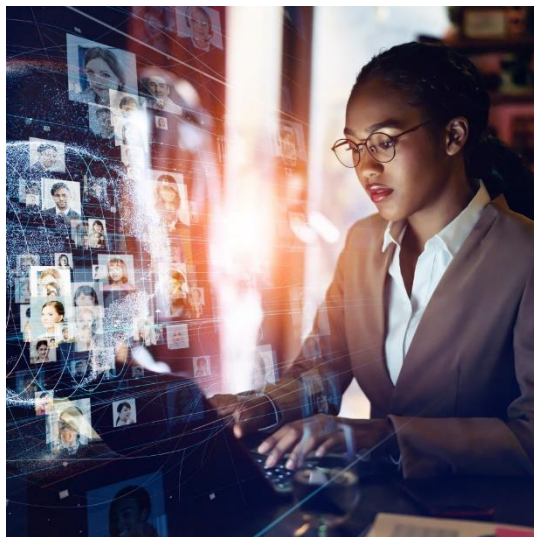


The spotlight on the pharmaceutical industry over the past year has garnered attention from a growing number of technology professionals interested in contributing their talents to vaccine and drug development. According to **Novartis research** compiled in June 2020, 72% of technology professionals were more likely to consider working in pharma as compared to six months prior. About the same number of professionals (73%) said their opinions of pharma have improved due to its response to the COVID-19 pandemic. Even more (85%) said the application of data science has been a crucial factor in pharma's rapid response.

Technology professionals with experience in data science, software development, security, information management, and artificial intelligence play an important role in the next generation of drug, biologics, and device development. In clinical research, they develop, test, and manage the tools that allow scientists, research sites, and sponsors to collaborate effectively.

As the amount of data swells, the industry needs these tech experts now more than ever. International Data Corporation (IDC) predicts that by 2025, the global DataSphere will grow to 175 zettabytes—the equivalent of 175 trillion gigabytes. IDC estimates healthcare and life sciences data comprise about 7% of the enterprise DataSphere.

**Clinical Research Tech Opportunities**

This is a defining time for pharma and for clinical research. COVID-19 set an example for how digital technology can improve the clinical research experience for researchers, patients, and physicians. Because of COVID-19, decentralized trials were widely adopted much faster than expected, and by all indications, they are here to stay.

The industry needs people who know how to manage data generated by decentralized trials. That includes data from telemedicine platforms, home health nurses, patients' mobile devices, and physicians. The researchers who design protocols for decentralized trials may know what they need from a scientific perspective, but they rely on technical professionals to build the systems that support those needs.

For example, a protocol may allow sites to conduct patient visits over the phone, in person at patients' homes, by videoconference, and in person at the clinic. To make that happen requires someone with the technical expertise and critical thinking skills to consider those components collectively and individually, and to implement one or more systems in support of any combination of those modalities.

With increased use of electronic source (eSource), whether it be electronic patient-reported outcomes (ePRO), electronic clinical outcome assessment (eCOA), or electronic direct data capture (DDC), clinical research sites also need technology professionals to assist with implementation and management. As the virtual clinical trial model is adapted more widely, sponsors, contract research organizations, and sites need technology professionals who can test, manage, and troubleshoot telehealth platforms, eSource platforms, electronic data capture (EDC) systems, medication management software, and remote patient monitoring.

Many drug and medical device developers and their vendors have a growing need for clinical database design, data operations, development, infrastructure (DevOps), and programming professionals. To succeed in a tech or tech translation role at these firms requires a careful bridging of clinical research knowledge and technical expertise through cross-functional collaboration.

Why is clinical knowledge important? When we subject a study-specific build to user acceptance testing (UAT), for example, we run through what a patient, caregiver, investigator, and/or site coordinator will see and use when participating in a clinical trial. The clinical database designer needs to translate a protocol's schedule of activities, including unexpected activities and visits, into technical requirements. Working with technical departments, the designer ensures that the solution supports the conduct of the clinical trial. Dual clinical-technical knowledge would be helpful in most clinical research technology positions, but it is not required.

Russell Reynolds Associates interviewed digital and technology leaders at 10 of the largest global pharma companies. It found only 25% of chief digital officers (CDOs) have a background exclusively in life sciences. The report also cited a trend toward bringing in tech leaders from outside the life sciences industry to fill newly created CDO roles. In addition, four out of 10 pharma companies have elevated digital and technology leadership to an N-1 level role.

As with upper management, recent graduates with either data science, information technology, or clinical research education have their pick of career opportunities. For example, a Ranstad report found demand for clinical research associates and trial managers grew by 46% between mid-2019 and mid-2020.

**Learn as You Grow**

For nonexecutive tech professionals, healthcare, medical, or science experience will give you a competitive advantage, but you don't need to run out and earn a medical degree to get a job in the field. Passion, a willingness to learn, and a strong work ethic will take you far.

Take initiative to learn the skills you're missing. Ideally, you can do this on the job. One of our employees, Caitlin, joined our quality organization straight from a clinical research program. Her hard skills were solid, but she needed to find her voice when communicating with the team. She worked on her communication skills, and as a result, she was promoted in the quality organization and then moved into a customer-facing role as a lead clinical database designer.

On the technical side, our eSource developers learn how patients and clinicians use the technology and how that technology impacts patients' lives. That knowledge drives their "why."

They can see how they're part of something bigger than the code they develop or the database they create.

**Be Prepared for Ebbs and Flows**

While many companies offer generous benefits packages, the work-life balance within them ebbs and flows. Clinical trials are cyclical and are driven by funding and interactions with regulatory agencies. During spikes in activity, the delivery team is prepared to work harder and longer; it is important to recognize the importance of self-care during these times and employ individualized practices that prevent burnout.

**Advice for Tech Professionals**

For those interested in moving into the technology side of clinical trials, consider these tips to land an interview or a job offer:

- **Apply for an internship.** Even mid-career professionals can benefit from internships. If you can manage it financially, a short-term internship will help you gain valuable on-the-job experience. It may also turn into a full-time position.
- **Make new connections.** Reach out to technical or clinical research professionals to ask questions about the industry or their job. Leverage LinkedIn connections, professional organizations, and personal connections. When a position has 1,000 applicants, your connections will help you move toward the front of the line.
- **Follow your passion.** Many people get into healthcare, medicine, and life sciences because they want to make a positive impact on the world. Where does your passion lie, and how can you combine it with your existing skills? That passion will help escalate your career much faster than chasing a salary.
- **Show your value.** During interviews, focus less on what you've learned and more on how you can bring value to the organization. Show that organization you have the initiative and the skill set they're looking for; be ready with your own "elevator pitch."

Technology professionals who want to take part in the digital transformation of clinical research have numerous opportunities available. Follow your interests and seek out opportunities to bring value, and you'll soon find yourself in a challenging, rewarding career.



**Alexis Gabard** is Director of Study Operations for Clinical Ink, where she delivers high-quality, customized projects to internal and external stakeholders, including executing and managing development of enabling technology from concept to close. She oversees study design requirements and specifications, study build and programming, study configuration and testing, UAT, study deployment and updates, and process improvements.

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PRESCRIPTIONS FOR BUSINESS

## What Makes a Successful BYOD Strategy in Clinical Trials?

Jonathan Andrus

The global COVID-19 pandemic wreaked havoc on clinical trials everywhere. By February 2021, research by GlobalData{1} indicates clinical trials being conducted by more than 1,100 U.S. and European organizations were adversely affected. As a result, virtual clinical trials and bring-your-own-device (BYOD) clinical trial models have come into their own.

BYOD, a strategy of installing electronic patient-reported outcome (ePRO) tools on patients' own devices, has been in use for years. However, by necessity, the ongoing public health crisis has resulted in faster, broader support for this powerful, patient-centric clinical data-capture solution.

When 81% of Americans own smartphones and are more likely to use them reliably than provisioned devices,{2} it makes sense to incorporate personal devices into clinical trials wherever feasible. The result is often shorter timelines and more cost-efficient clinical trials that yield better data through simplified ePRO collection that is less of a burden on patients.

This article addresses considerations for ensuring a successful BYOD strategy at all clinical trial stages.

**Let Your Patients Choose**

Patients are crucial in clinical trials. To encourage clinical trial enrollment and retention, we need to understand patient needs, desires, and dislikes. Do patients want BYOD? Is it always suitable?

Several years back, a study by Clinical Ink with ICON and Novartis found that 45% of clinical trial participants preferred a BYOD approach over using a provisioned device. About 40% didn't have a preference and would have been happy with BYOD or a provisioned device. Only 15% preferred a provisioned device (see Figure 1). Even among patients over 60, more than 82% would have accepted BYOD.{2}

**Figure 1: 45% of Subjects Found BYOD More Convenient Compared to 15% Who Preferred a Provisioned Device and 40% Who Had No Preference**
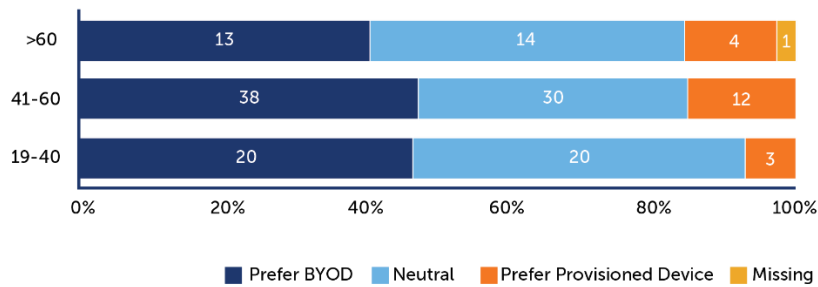


We then asked about patients' ease in using their smartphones. For instance, would they feel comfortable if we asked them to download an app?

The result was clearly in favor of BYOD. Around 90% to 95% of patients were willing to use their own device in a study, and the vast majority also believed they would be able to download the app without assistance (see Figure 2). Downloading an app does not appear to be a great barrier. Most participants would likely not require assistance.

**Figure 2: Most Patients Are Willing to Use Their Own Device and Able to Download an App for a Clinical Study**
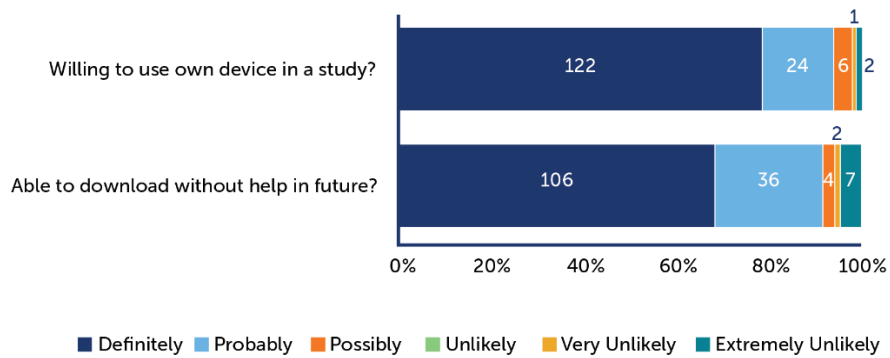


Knowing that older patients might be less comfortable with technology in general, we wondered what we could offer that might help. One finding was that older patients tend to have bigger devices with larger screens. We realized we were making it more unattractive for some patients by asking them to use a device they are not familiar with and that has a smaller screen than they're used to. This suggests that providing larger devices with bigger screens for these patients might make it easier for them to participate and remain in a study.

Overall, to maximize enrollment and retention, we need to do our research and develop systems and processes that allow patients as much choice as possible in how they participate

and provide us with their data. In the case of BYOD, the majority of patients are already on board. For those who are not, we can provide devices.

**Understanding the Regulations for BYOD**

What do the regulators say about BYOD? Officially, not much. From the compliance perspective, the 2017 Q&A document 21 CFR Part 11 from the *Code of Federal Regulations*{3} does not differentiate between BYOD and provisioned devices. However, anecdotally, certain concerns have come to light in private communications and conversations with the U.S. Food and Drug Administration (FDA). These concerns fall into three categories:

- Data privacy
- Inclusivity (we don't want to exclude any patients due to the lack of an adequate device)
- Technical considerations

The first and last points can be addressed through existing technology solutions on a study-by-study basis. Regarding inclusivity, it's important to remember that when we talk about a BYOD trial, it's never 100% BYOD. You will always need to provide a few devices to support patients who can't bring their own and possibly help with data plans as needed.

Concerns we *don't* hear at this point from the FDA are about the equivalence of paper and other kinds of questionnaires to BYOD. Crossover studies{2} have demonstrated that equivalence is generally not a problem. In addition, there is a push by the FDA to move away from paper-based trials.

Lastly, though we continue to make the technology more sophisticated, fundamentally, BYOD is not new. We've used interactive web response systems (IWRS) in ePRO for a long time. Common concerns, such as what happens to data if a patient loses their device, deletes the app, upgrades their phone, or has insufficient bandwidth have been put to rest. The apps are different now, but the concept is the same.

To date, numerous studies have made successful regulatory submissions with BYOD-captured primary endpoint data. While BYOD is not suitable for every situation, many Phase I–III studies

can benefit from greater feasibility, faster recruitment, and better retention with significant savings in time and cost by taking a BYOD approach.

**An Illustration: Leading Firm Switches to BYOD Mid-Trial**

Mid-pandemic, a leading pharmaceutical company conducting traditional Phase II and III trials needed to pivot quickly to allow 2,000 patients at more than 250 sites to report outcomes from home for central nervous system (CNS) studies, using their own devices.

The Ask:

- Handle CNS-related protocols with many standardized assessments and scales.
- Design, develop, and deploy ePRO for four studies—two in Phase II and two in Phase III.
- Enable patients to use their own devices (BYOD).
- Provide alternatives for patients unable to participate by BYOD means.
- Execute the changeover in data collection practices rapidly.

The Answer:

- Design, develop, and deploy four studies in 10 days.
- Build 10 different collection forms for home use (SF-36, HADS, LEC-5, etc.).
- Get early buy-in from license holders to prevent bottlenecks.
- Create engagement content for all four studies.
- Perform agile study development with limited user acceptance testing.

In our experience, driving collaboration from the start is the best way to deploy faster and ensure user-friendly results. This patient-centric, BYOD setup helped improve patient retention and pave the way for enrollments at a time when no one wanted to visit a clinic.

**Rapid, Agile, Collaborative Study Development**

The ability to build all the patient-completed forms and engagement content in 10 days for all four studies relied on an agile design and development process (see Figure 3).

This approach does require a lot of coordination. After initial discussion of requirements, an agile BYOD design effort moves quickly to configuration of a prototype. Both teams gather— in this case, virtually—for the collaborative effort. Design and project management teams walk

the sponsor team through the design to make sure its members have been able to download the study app onto their own phones. An interactive user acceptance testing meeting follows.

The sponsor team provides feedback instantly to the build team. The build team immediately refreshes the design and redeploys it to be tested again. This iterative design and development process yields a high-performing, pressure-tested, ready-to-deploy build in a very short time. Once the final updates are made, the specifications are generated.

**Figure 3: An Agile eSource Ecosystem Build Design**
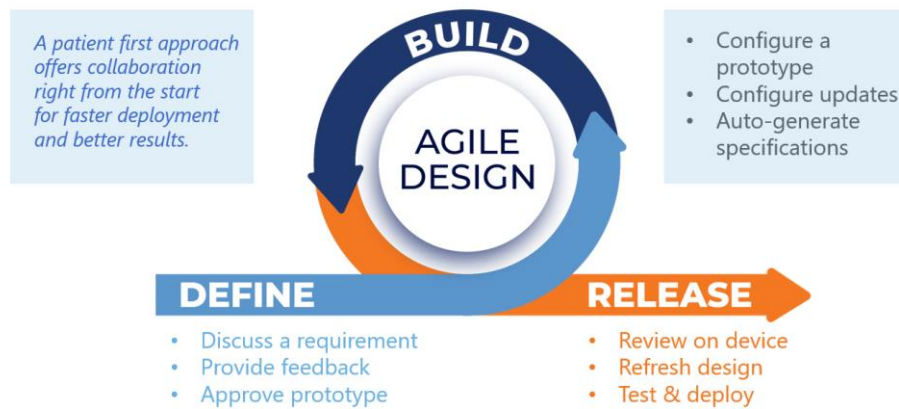


In all, an agile methodology:

- Means build first and output the specifications after the fact.
- Requires team members to be available to review interactively.
- Allows for a configurable, immediate, and interactive build.
- Involves immediate updates, based on feedback.
- Is tech-transfer-enabled.

This approach has been used in more than 100 studies across varied therapeutic areas.

**Adherence, Retention, and Data Quality Hinge on Engagement**

BYOD is a channel not only for collecting patient-reported outcomes, but also for communicating directly with patients. Because people tend to keep their own smartphones with them most of the time, it is a reliable tool. Beyond ePRO, a patient's device can be used to:

- Schedule event diaries, such as a dosing diary.
- Present simple to-do lists.
- Provide task reminders.
- Send upcoming visit reminders.
- Offer fast facts about the study, including goals and objectives.
- Thank them for taking the time and making the effort to participate.

Messaging and reminders help keep patients engaged in a study and improve their likelihood of reliably fulfilling protocol requirements.

**Realize BYOD Can Be an Efficient Strategy**

Certainly, patient centricity in clinical trials and elsewhere is in fashion as well as being a current interest of the FDA. More than these considerations, it eases enrollment by making trials more attractive for patients.

As the quintessential, patient-preferred solution, BYOD also helps with retention and more complete data collection by alleviating the burdens of ePRO and increasing the likelihood that reminders and other patient engagement strategies will be received in a timely fashion.

Furthermore, as part of the decentralized trial toolkit, BYOD allows broad and diverse patient participation as it always includes the option of provisioned devices for patients unable to take advantage of BYOD. Finally, with an agile, rapid build strategy, sponsors can maintain or even reduce timelines—all while saving money on smartphone purchases. For a large trial, this can add up to hundreds of thousands of dollars.

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SCIENCE & SOCIETY

# Advancing Africa's Clinical Research Leadership

Yonnie Otieno; Al O. Pacino
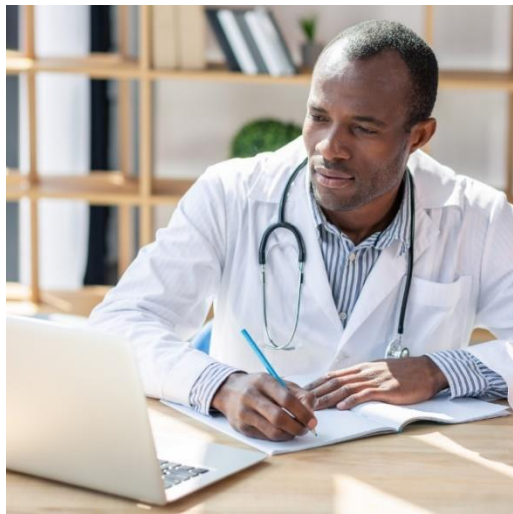


*The COVID-19 pandemic is redefining health systems beyond its origins in 2020. Rapid changes are continuing to occur in the use of digital health technologies to fast-track delivery of personalized medicine. Providers of clinical education and course learning ought to be open to collaboration when it comes to the distribution of trainings that sponsors require clinical trials team members to take. Moving forward, online learning plans are including incentives for professional education and certification training for personnel to attain the highest level of regulatory excellence. The survival of African sites is counting on the delivery of research training, connectivity, and security. Online access can improve healthcare compliance, ensure privacy of data, and upscale training standards that address the health of populations in the region.*

## Acknowledging Successes and the Continued Need for Connectivity

As emerging technology enhances medical care and clinical research, over the next several months sponsors and other biopharmaceutical firms, universities, contract research organizations, hospitals, and other organizations are preparing executive personnel to integrate even more applications. Use of telemedicine, artificial intelligence, deep mind learning, and digital therapeutic tools inform medical policies and public health actions.

Presently, more digital-based training is applied and optimized in the search and design of innovative drugs, life-saving vaccines, and medical test devices. A sense of urgency to adopt the use of digital therapeutics and peripheral devices in centralized and decentralized research trials has grown among leaders. Simultaneously, care is being redesigned to address how patients are managed, diagnosed, and monitored for disease progression. A new approach of setting up

robust digital/eLearning libraries as a catalyst for capacity training and education can contribute to shaping global public health.

In this context, long-term strategic and social investment in education and training are critical for professional growth on the African continent. Collaborations between educational institutions and research development for organizations can provide modern access to continuing medical education (CME). A track record of achieved CME for principal investigators and other education for clinical trials team members, all of which should include globally standardized competencies, is key to the perceived feasibility of a site for participation in sponsored studies.

Existing global collaborations have resulted in the development of tools that update researchers about major diseases, indications, and therapies. The sharing of medical research education and training provided breakthroughs in advancing on mRNA and viral vector vaccine technologies. Accessing new research therapeutics is important for novel vaccines development, and ultimately, the handling of other diseases.

Meanwhile, efforts toward educating the public about research principles and the need for participation in clinical trials are still needed. The delivery of systems that aid in compliance and implementation will bring more opportunities for all. The ability to adhere to new privacy laws establishes trust more easily between clinical research and healthcare institutions. Over time, staff and management benefit from efficiently managing end-to-end protected digital processes that leave no patient behind.

**Missions for the Future**

It takes time to attain the highest competencies and qualification for all levels of research professionals. The journey to medical excellence is achieved through the transference of lifesaving skills and sound medical actions to patients.

Countries throughout Africa benefit from incentivized educators and organizations that develop tools to track learning and manage capacity for various personnel. The attainment of high-precision skills by clinical research professionals is key in managing current and future medical emergencies, epidemics, and pandemics. New connective platforms, along with reliable internet

infrastructure, allow new opportunities for many African countries. Education and training can be translated into dozens of languages to provide a standard care for all patients.

Accessing and implementing modern learning tools, combined with high education standards, will produce quality practice. While practical training such as the use of basic tools (examination, summary notes, and prescriptions) to instruct medical actions are critical, global collaboration is imperative for the African region. One of Africa's goals ought to be the safe integration of professional codes and ethical standards that protect everyone equally—across races, religions, and political divide.

Last year and into this one, we relied on the adept responsiveness of clinical researchers, pharmaceutical breakthroughs, and vaccines treatments to see our way through challenging times. Moving forward, there is a growing possibility for Africa's nations to establish themselves among the leaders in clinical discovery.



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TRIALS & TECHNOLOGY

## How the CRO Shift to Digital is Transforming Clinical Research

Jim Reilly



Clinical transformation accelerated during COVID-19 to speed trial execution. As companies raced to find treatments and vaccines, life sciences researchers came together to deliver innovation faster than ever. Despite these leaps forward, the industry recognizes the pace is not sustainable due to the regulatory changes and cross-company collaboration it took to get there. To drive long-lasting change in trials, more work remains to modernize clinical systems, and contract research organizations (CROs) are leading the way.

CROs are taking significant action to speed study execution by investing in new digital strategies and technologies that bring together study processes in trials. In fact, 90% of CROs say they have initiatives in place to unify clinical operations, according to a recent study.{1} These efforts are driving more streamlined and connected ways of conducting research.
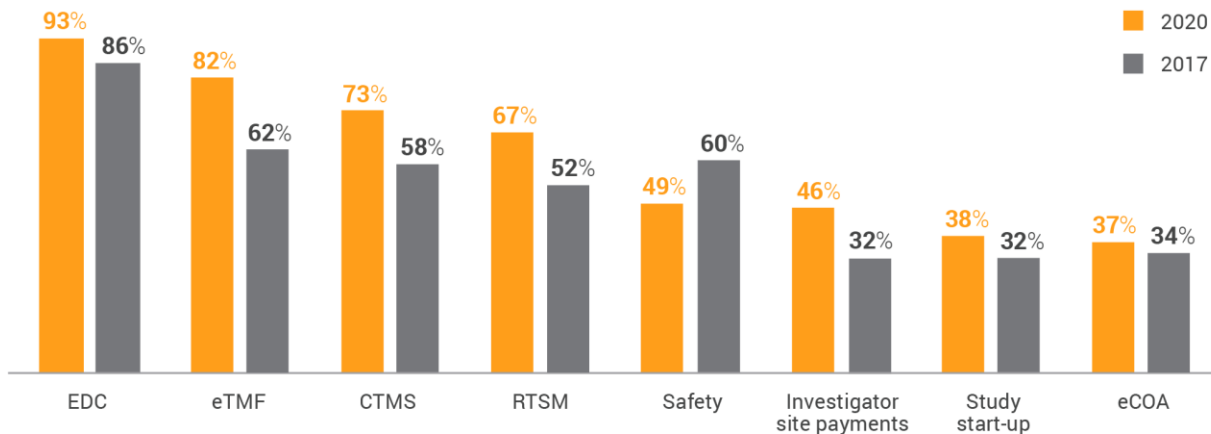
By increasing efficiency in major clinical areas and improving collaboration across the trial ecosystem, CROs are advancing the industry toward patient-centric digital trials. The ongoing modernization elevates the industry to a new level of connectivity that will benefit life sciences and patients for years to come.

**Modernizing Across the Clinical Landscape for Faster Execution**

CROs are implementing digital approaches across the clinical spectrum to speed trials. New solutions are making it easier to modernize specific areas, and there's been an acceleration in the adoption of purpose-built applications.

### Applications Used to Manage Clinical Studies
Base: CRO Respondents, 2020 N=124, 2017 N=50

| Application | 2020 | 2017 |
|---|---|---|
| EDC | 93% | 86% |
| eTMF | 82% | 62% |
| CTMS | 73% | 58% |
| RTSM | 67% | 52% |
| Safety | 49% | 60% |
| Investigator site payments | 46% | 32% |
| Study start-up | 38% | 32% |
| eCOA | 37% | 34% |

**Study start-up** is an area with significant potential to speed trial cycle times and improve overall efficiency in studies. This explains why 38% of CROs are using purpose-built study start-up applications, signaling a shift from manual methods like spreadsheets and e-mail to advanced solutions. The key drivers accelerating change among CROs are improving start-up times (73%) and reducing manual processes (52%). These advancements in study start-up will have a positive downstream impact on trials as more sponsors outsource early trial activities like site feasibility and selection to CROs.

In **data management**, one of the earliest areas to implement process automation, a growing number of leading CROs are looking to innovative clinical data management applications to run higher quality studies for sponsors.{2} This new breed of solution enables study builds in six weeks or less and delivers the agility to satisfy even the most complex data requirements.

CROs are also mitigating delays and issues in studies much quicker than ever before. With complete study oversight, **clinical trial management systems (CTMS)** empower CROs to identify problem areas and make instant decisions. This form of proactive trial management increases efficiency for CROs and research sites alike. The shift from spreadsheets and homegrown systems to digital clinical trial management has been key in standardizing study processes for faster execution.
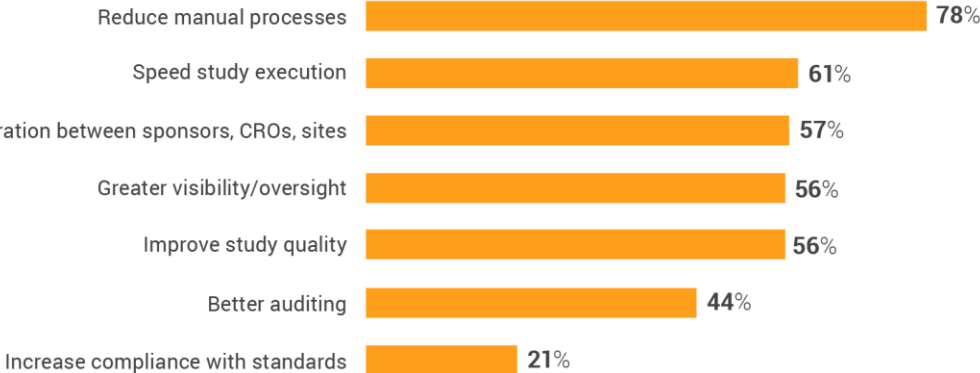
Trial master file (TMF) management is undergoing vast transformation as more CROs move to **eTMF** applications with advanced digital and collaboration capabilities. Modern eTMF is driving positive improvements for CROs in TMF accuracy (70%) and completeness (63%) over other methods like paper and local file systems. eTMF is a vital tool for improved information sharing and better collaboration in trials.

**Automating Information Exchange for Improved Collaboration**

An overreliance on paper and manual processes in clinical trials make it difficult to share information with key stakeholders. The growing complexity and increasing volumes of data in studies are making it even harder. For CROs, streamlining information sharing is a top priority to reduce manual processes (78%), speed study execution (61%), and improve collaboration with sponsors and sites (57%).

## Top Drivers to Streamline Information Exchange

Base: Total CRO respondents, N=124

| | |
|---|---|
| Reduce manual processes | 78% |
| Speed study execution | 61% |
| Improve collaboration between sponsors, CROs, sites | 57% |
| Greater visibility/oversight | 56% |
| Improve study quality | 56% |
| Better auditing | 44% |
| Increase compliance with standards | 21% |

CROs are breaking down the paper barriers by adopting solutions that automate information flow. These new technologies connect investigator site systems with CRO clinical operations to streamline processes like safety letter distribution and study closeout transfers. By transforming information exchange from manual and paper-based to digital and automated, CROs are improving collaboration in studies.

Investments in decentralized approaches are also improving information sharing across trial stakeholders. For example, informed consent has been traditionally managed manually on paper. Solutions like eConsent digitize the process; eConsent makes it easier for patients to understand and provide informed consent and for CROs and sites to share information. More CROs are enabling sites to use eConsent for a simpler, paperless consenting process.

**CROs are Digitizing Processes and Connecting Systems for Faster Trials**

Sponsors outsourcing clinical trials expect to gain access to innovative technologies and approaches. To offer differentiated services and deliver efficiencies to sponsors, more CROs are digitizing processes and connecting systems. During the pandemic, this proved crucial to ensure continuity in trials. Many companies experienced delays because study monitors could not verify data at research sites. The CROs that unified study documents and data, and had the digital capabilities to enable remote monitoring, kept trials moving forward.

Looking ahead, these same organizations embracing digital will speed trials and lower overall costs, delivering transformational change for the industry. We're only at the tip of the iceberg, but the advancements will be swift. Thank you, CROs, for moving the industry toward future trials that are digital, connected, and fast.

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OVER THE TRANSOM

# ISO New and Exciting Acronyms FTW

Gary W. Cramer
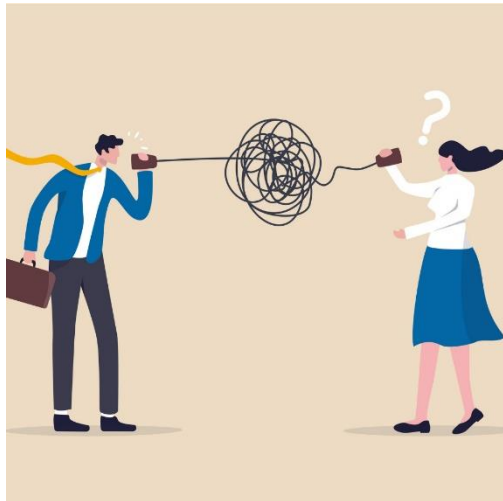


One thing you'll hear over and over when seasoned clinical research professionals start talking about how they broke into the field is the astonishment (and trepidation) they felt as they began to scale the mountain of acronyms being tossed about so casually by the veterans around them. Even as someone who was long used to having to become an "instant expert" on topics that I was covering in my former newspaper, magazine, and public relations jobs, I was a little stunned upon arriving at ACRP and having to sort out my CRAs, CRCs, and CPIs from my CROs, CRFs, and CTAs.

In keeping with the technology theme of this issue, and in the spirit of throwing more acronyms at you than any human should have to face in a single column, here are excerpts from some otherwise timely news items that have crossed my desk recently from stakeholders in the clinical research enterprise (no endorsements implied).

**The Rise of DCTs is Disrupting Traditional Patient Recruitment**

As the pandemic has accelerated the adoption of decentralized clinical trials (DCTs), SubjectWell CEO Ivor Clarke has been thinking about how this manner of conducting trials challenges our current definition of recruiting, why centralized recruiting is critical for success with DCTs, and how much patients actually like concierge services, fewer in-person visits, and the technology and mobile apps that reduce their burden of trial participation.

In an April blog post, Clarke notes how, in a [SubjectWell patient survey](#) from October 2020, the following accommodations found in DCTs were rated as extremely or very important: study medicine delivered to the home (75%), remote communication with doctor (74%), lab samples collected at home (68%), concierge services (67%), and mobile applications (67%). However, DCTs "put ownership of the patient relationship up for grabs," Clarke writes.

Traditionally, Clarke explains, "the recruiting relationship with patients stops with the referral, passing the responsibility to sites to shepherd patients though the study funnel." With fewer principal investigators and site coordinators involved, DCTs alter how patient relationships—tied to such matters as screening, informed consent, study compliance, and follow-up visits—are managed.

"It may be difficult to substitute the consistency and personal touch provided by sites to pull patients from screening to consent," Clarke notes. "Perhaps technology (eConsent, web prescreens, digital scheduling) will engage the patient and bridge the gap until a study contact is later assigned. Adding a patient-engagement step with education early in the recruitment process may be enough to keep patient trust and participation interest high."

For more information, you can read Clarke's [blog here](#).

**Expanding Decentralized Solutions to Bring Trials Closer to Patients**

Syneos Health and Medable in April [announced](#) a strategic partnership to bring clinical trials closer to the patient. Through the partnership, Syneos Health will gain access to Medable's digital platform for reducing physician burden, simplifying the patient journey, and collecting previously difficult-to-obtain data to speed therapies to patients across the clinical development lifecycle. In combination with Syneos Health's Illingworth Research Group mobile research nursing capabilities, the company believes the platform will enable it to engage more diverse populations and increase access for patients who previously couldn't participate in clinical trials.

Medable's platform delivers onsite and at-home access on any web-enabled device utilizing TeleVisit, TeleConsent, TeleCOA (that's for clinical outcome assessment, BTW [by the way]), and remote patient monitoring tools.

**EHR Usability Issues Linked to Nurse Burnout and Patient Outcomes**

Nurses and other clinicians rely heavily upon electronic health records (EHRs) when providing patient care. This includes clinical decision-making, care planning, patient surveillance, medication ordering and administration, and communication with other healthcare team members. While data show that EHR technology usability can put added burden on clinicians, the relationships between EHR usability and the job outcomes of hospital staff nurses and surgical patient outcomes have not been explored.

A new study from the University of Pennsylvania School of Nursing's Center for Health Outcomes and Policy Research has investigated associations between EHR usability and nurse job outcomes (burnout, job dissatisfaction, and intention to leave) and surgical patient outcomes (inpatient mortality and 30-day readmission). The study found that employing EHR systems with suboptimal usability was associated with higher odds of adverse nurse job outcomes and surgical patient mortality and readmission. In fact, EHR usability may be more important to nurse job and patient outcomes than comprehensive EHR adoption. The results have been published in the journal *Medical Care*.

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