## Clinical Researcher
## May 2021
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## *Careers and Challenges Behind the Clinical Trials Technology Curtain*

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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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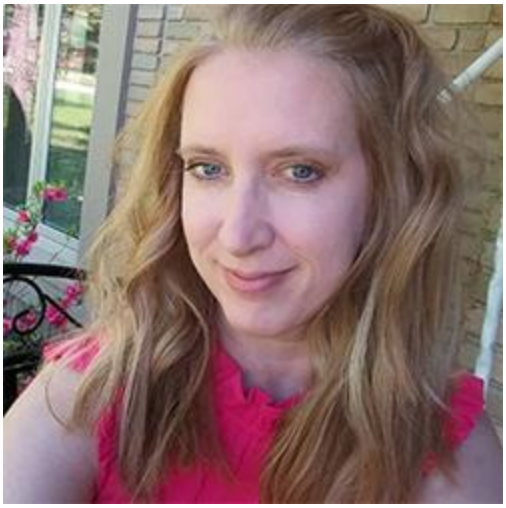


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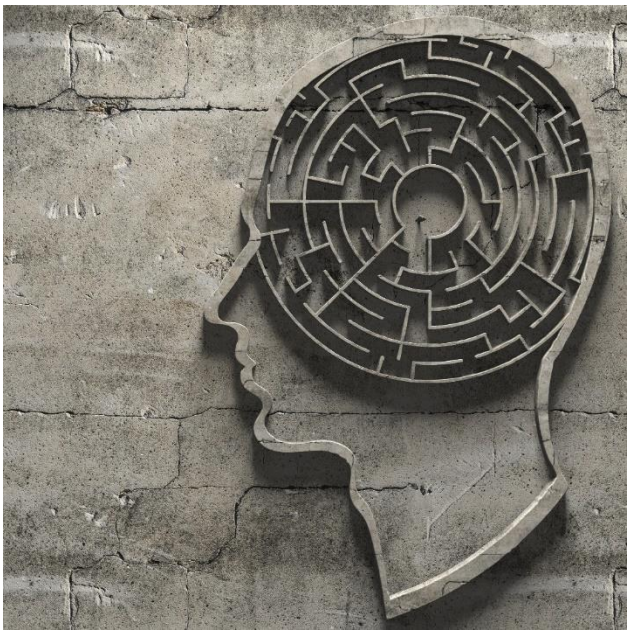
SPECIAL FEATURE

# 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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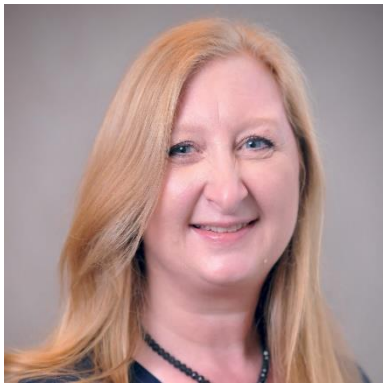


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**ACRP HOME STUDY**
**CLINICAL RESEARCHER—MAY 2021 (VOLUME 35, ISSUE 4)**
*Careers and Challenges Behind the Clinical Trials Technology Curtain*

Article #1: **The Pandemic Push to Virtual EHR Training and Optimization for Clinical Research**

LEARNING OBJECTIVE
After reading this article, the participant should be able to summarize the importance of training on electronic health record systems, the advantages they offer for conducting clinical trials, and how virtual training helped overcome obstacles to in-person training for the profiled academic medical center.

DISCLOSURES
Paula Smailes, DNP, RN, CCRP: *Nothing to disclose*

**1. Which of the following is noted as an important role of electronic health records (EHRs) in terms of data collection?**
a. Exposing areas of weakness in trial conduct for targeted investigator training.
b. Improving trial budgeting and contracting functions for increased site profitability.
c. Identifying improved outcomes and health savings from new interventions.
d. Reorganizing study coordinator schedules to maximize their productivity levels.

**2. What was the main challenge posed by COVID-19 where researcher training on EHRs was concerned?**
a. Finding trainers willing to still conduct training in classrooms.
b. Justifying training in light of high staff turnover trends.
c. Gaining regulatory approval to cease such training altogether.
d. Continuing training when physical distancing was necessary.

**3. What was the significant difference in the EHR training at the institution featured in this article before the pandemic versus during it?**
a. The method of delivery.
b. The cost to recipients.
c. The quality of content.
d. The learning outcomes.

**4. After six months of virtual EHR training, how did end-user satisfaction with the content and trainers compare to results before the pandemic?**
a. There were major differences for both measured areas.
b. There was little difference for either measured area.
c. Satisfaction with content was higher, but with trainers the same.
d. Satisfaction with trainers was lower, but with content the same.

**5. Which of the following was a recurring theme in evaluation comments from trainees after their initial virtual training?**

a. Requests for a new instructor.
b. Requests for one-on-one sessions.
c. Requests for simpler content.
d. Requests for longer sessions.

**6. Which of the following was noted as a benefit of the conversion from an instructor-led to an eLearning format for EHR training?**

a. A substantial return on investment is gained.
b. Unprepared learners drop out more quickly.
c. Investigators spend less time on mentoring.
d. Trainers are more likely to be qualified.

**7. Which of the following is used by the institution to ensure newly hired researchers are using the basics system features taught in the EHR training class?**

a. Simulated EHR system breakdowns.
b. Follow-up testing on EHRs during performance reviews.
c. Weekly pop quizzes on EHR functionality.
d. An EHR competency checklist.

**8. Which of the following metrics is featured in an EHR audit tool developed by the institution?**

a. Coordinator research certification status.
b. Institutional review board approvals.
c. Investigator review of adverse events.
d. Participant acceptance of possible placebo.

**9. What prompted researcher outreach and support for changes to their EHR usage habits as studies restarted at the institution?**

a. The medical center's EHR vendor stopped supporting the product it had been using.
b. Many principal investigators preferred that coordinators return to classroom training.
c. The institutional review board would not approve studies without EHR refresher trainings.
d. Many COVID-19 studies involved inpatient situations rather than outpatient ones.

**10. Who did the institution turn to for communications with research teams about quarterly updates to the EHR system?**

a. The medical center's public relations office.
b. "Super users" of the system.
c. A rotating roster of study coordinators.
d. The regulatory compliance unit.

[Test continues on following page.]

Article #2: **Overcoming Perceived Implementation Barriers to Decentralized Trials**

LEARNING OBJECTIVE
After reading this article, the participant should be able to describe why decentralized trials have experienced growth recently, how they have matured historically, and expected trends for their future use.

DISCLOSURE
Alison Holland: *Nothing to disclose*

**11. Following its rapid growth during the pandemic, what are the expectations for the future adoption of decentralized clinical trials (DCTs) by the clinical research enterprise?**
a. Growth is expected to come to a halt by late 2021.
b. Growth is expected to pause until a resurgence in COVID-19.
c. Growth is expected to continue beyond the pandemic.
d. Growth is expected to be followed by a rapid decline by 2025.

**12. Which of the following is a major shortcoming in traditional trials that DCTs can help overcome?**
a. Lack of access to patients.
b. Declines in funding from sponsors.
c. Poor acceptance from regulators.
d. Underqualified research teams.

**13. Which of the following is noted as an advantage of using eConsent tools when conducting DCTs?**
a. They require no training for study coordinators to use properly.
b. The costs of their use can be passed on to the trial participants.
c. Principal investigators do not need to be involved with them.
d. They reduce or eliminate manual or repetitive data entry tasks.

**14. What are researchers finding about the willingness of certain patients to use technology in trials?**
a. Patients with higher income levels are less satisfied with most technology used for trials.
b. Patients, including older generations, are more familiar with technology than expected.
c. Most patients in DCTs will initially refuse to use the technology tool expected of them.
d. Patients in rare disease trials are more eager to try new trials technologies than others.

**15. Which of the following technologies was utilized in the first fully virtual clinical trial?**
a. Digital pills
b. Smart watches
c. Mobile phones
d. iPods

**16. The author recommends researchers conducting DCTs leverage which of the following technology tactics?**
a. Using a single platform with built-in flexibility.
b. Never allowing patients to use their own devices.
c. Insisting the sponsor supplies made-in-U.S. tools.
d. Patients willing to purchase inexpensive devices.

**17. What does the author recommend to ensure that consistent and comparable data can be gathered from patient devices in multinational studies?**
a. The devices should each be manufactured within the separate countries.
b. The patients should be in touch with each other across national borders.
c. The patients should all enter data into their devices in the same language.
d. The devices should be identical to one another regardless the country.

**18. Which of the following is noted as an important consideration for informed consent in DCTs?**
a. Institutional review boards are less stringent about informed consent in such trials.
b. Only principal investigators should conduct the informed consent process in DCTs.
c. It should be conducted in the same way and with the same guidelines for all patients.
d. DCTs can be expected to make informed consent unnecessary in the near future.

**19. What is the name of the organization that formed recently to advocate for more DCTs?**
a. National Center for Digital Health Trials
b. Decentralized Trials and Research Alliance
c. Center for Devices and Radiological Health
d. Clinical Trials Transformation Initiative

**20. Which of the following is noted as being crucial to compliance with data regulations during DCTs?**
a. Data mapping
b. Data mining
c. Data capture
d. Data integrity