



Clinical Researcher

The Authority in Ethical, Responsible Clinical Research

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Mapping the Way to Modern Trial Design, Management, and Analysis

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Clinical Researcher

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EXECUTIVE DIRECTOR'S MESSAGE

Community, Connections, and Intersections

Susan P. Landis, Executive Director of ACRP



As this issue goes online, it has already been nearly two months since many of you flocked to Orlando to join in on all the goodness that was our ACRP 2022 gathering. If you were fortunate to attend in person or viewed the [highlights on our website](#), you most likely can tell it was a successful conference—and fun! More than 1,000 clinical researchers convened to listen and learn from more than 80 speakers delivering nearly 60 sessions and three pre-conference workshops. Our sponsors were numerous, our social networks were buzzing, and the spirits onsite were high as our amazing community of clinical researchers reconnected live and face-to-face for the first time in three years. What a blast!

ACRP's community showed up big time in May, too. In celebration of [Clinical Trials Day](#) on May 20 (an event with which more than 124,000 clinical researchers around the world engaged in through our robust clinical research social media network), you helped to raise nearly \$64,000 as part of the latest [ACRP Ride for Diversity](#). The ride was a six-day, 334-mile bicycle trek from Pittsburgh, Pa. to Alexandria, Va., ending on Clinical Trials Day and led by Association Board of Trustees Member Sergio Armani, from Advarra, and Velocity's Rick Fisher. We had strong financial support for the ride from many individuals and major corporate backers this year, including Elligo Health, Medrio, Meridian, Pfizer, and Velocity. In this second year for the event, we raised the bar and reaped rewards that will allow ACRP to fund scholarships for education in clinical research and to support the efforts of our [Diversity Advisory Council](#). Thank you!

But Wait, There's More...

Whether in person or through virtual means, ACRP is committed to recognizing and celebrating what we know is a rich and diverse community of clinical researchers. This year, we have already hosted campaigns that celebrated Latinx heritage, highlighted voices from ACRP's Black members, and honored Asian American and Pacific Islander Heritage Month.

This month, for the first time, we are recognizing our LGBTQ+ community during Pride Month. [A Gallup poll](#) recently revealed that a record number of U.S. adults self-identify as lesbian, gay, bisexual, transgender, or other than heterosexual. This figure doubled from 2012. Twenty-one percent of Gen Zers—or Zoomers—who now have reached adulthood, self-identify as LGBTQ. Why should we care? Because this next generation is both a part of our community of clinical researchers and a part of our population that needs to be reflected in clinical trials and studies. As we considered what to include in our Pride Month campaign, I found it helpful to ask, “What do we need to know?” As the answers came in, I learned something, and I hope you will, too—[learn more here](#).

Nowhere are community, connections, and intersections more important than they are in terms of improving diversity, equity, and inclusion in clinical trials. Along with many organizations in our industry, members of ACRP's Content Committee responded to the [U.S. Food and Drug Administration's new draft guidance](#) on improving enrollment of participants from underrepresented racial and ethnic populations in clinical trials. The focus of [the guidance](#) is to encourage sponsors to develop race and ethnicity diversity plans early in a trial or study's development. Good, but a lot more needs to be done.

Meanwhile, the National Academies of Sciences, Engineering, and Medicine released [a comprehensive report](#) for improving representation in clinical research. The conclusions can be [read here](#). They go beyond encouraging sponsors to have a plan to document critical recommendations, such as by investing in building trust with underrepresented and excluded communities, recommending medical journals and publications require information on representation in trials for submissions, incentivizing community providers to enroll and retain

participants, and developing explicit guidance for providing equitable compensation to clinical research participants and their families.

Getting to the Bottom Line

Recommendations and guidances are important, but we know—*you know*—that recognizing people who participate in clinical research, be it as a researcher or a patient, begins within your own community. Thank you for being a part of our efforts to strive to recognize you and your colleagues equally. In turn, we encourage you to take steps at your study site, site management organization, academic institution, contract research organization, patient advocacy group, clinical trials technology vendor organization, sponsor organization, or wherever you are in the clinical research enterprise to develop and drive initiatives that will improve diversity, equity, and inclusion in your community for the benefit of all.

As always, my heart-felt thanks to you for being a member of ACRP and for supporting our collective efforts to ensure excellence in clinical research.



PEER REVIEWED

Finding Perspective and Identifying Research Best Practices Amid the Ongoing COVID-19 Pandemic

Deanna M. Golden-Kreutz, PhD; Angela O. Sow, MACPR; Michelle R. Bright, MA;
Brad H. Rovin, MD



For more than two years, the COVID-19 pandemic has affected every sector of the global economy, including the clinical and translational research enterprise.^{1} Academic medical centers (AMCs) have faced the challenges of an apprehensive health system concerned with maintaining patient and healthcare worker safety with an emergent call to advance COVID-19 knowledge through research.^{2} Even as AMCs implemented investigational approaches and treatments, the pandemic exposed the need for new and

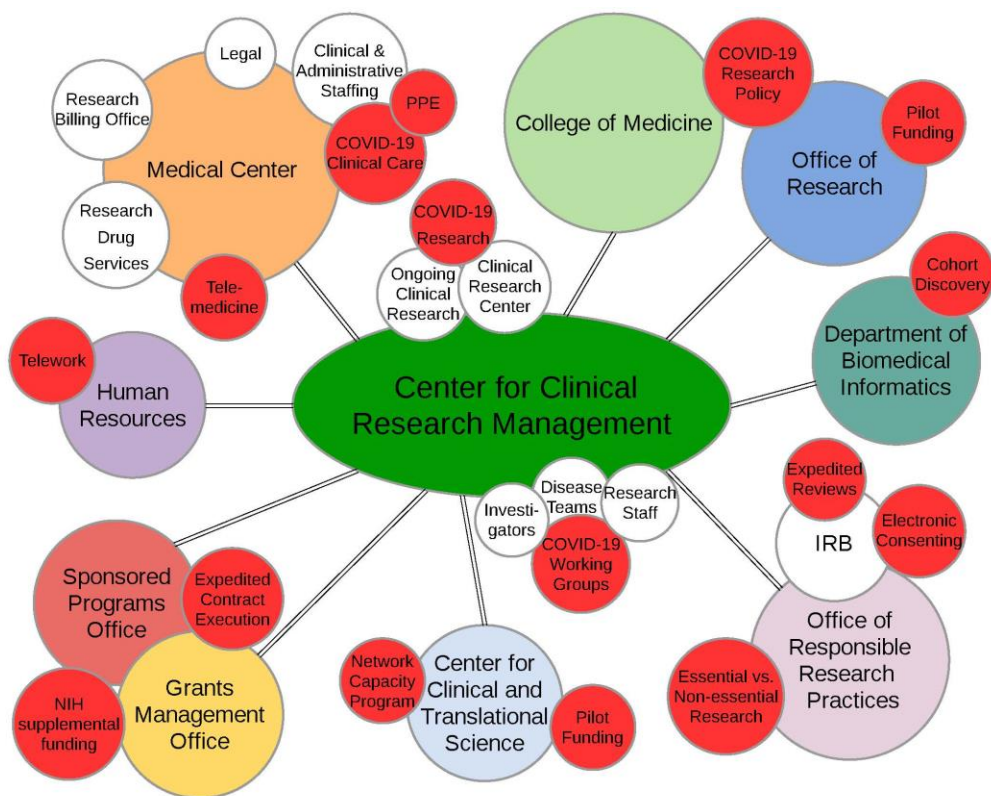
broader strategies in order to successfully operationalize and manage research as both an urgent and now clearly a long-term response.^{1,3} However, a review of the pandemic's impacts on the larger clinical research landscape is needed to fully understand the environment in which newer research processes have been and continue to be implemented.

Importantly, this article illustrates the wide-ranging impact of COVID-19 on research processes and associated best practices that have emerged to manage these impacts on the research environment at The Ohio State University Medical Center. Four overarching key strategies are highlighted: 1) leveraging existing research management infrastructure; 2) establishing a COVID-19 research policy; 3) developing multidisciplinary research working groups; and 4) strengthening connections among institutional research stakeholders. These strategies demonstrated success in the initial response to the pandemic and have remained critical for research management throughout the ongoing pandemic.

Leverage Research Management Infrastructure

The pandemic has permeated academic and administrative operations. Figure 1 illustrates the impact of COVID-19 on research processes at the institutional level as unprecedented shifts in routine clinical practices continue to be reflected in updated and ever-changing federal, state, and local university guidelines for research.

Figure 1: COVID-19's Impact on the Research Landscape



The literature to date has discussed how some AMCs mobilized their research response through the creation of a COVID-19 oversight group located within their College of Medicine, Office of Research, Clinical Translational Science Award Center, or some combination of these institutional entities.^{4} Our AMC leveraged a centralized administrative infrastructure for managing non-cancer human subjects research, the Center for Clinical Research Management (CCRM), to rapidly oversee and implement COVID-19 research. The CCRM, supported through

The Ohio State University's College of Medicine, strategically aligns resources and research personnel with the needs of investigators and disease-specific research teams.

The connectivity of the research infrastructure with the larger landscape and multiple stakeholders is demonstrated in Figure 1. The red circles highlight the pandemic-related impacts and/or adjustments that have been necessary to successfully implement and maintain overall research activity. As such, the infrastructure of the CCRM has rapidly addressed the continuously evolving direction of COVID-19 research, offering an organized pathway for conducting research while also managing these efforts with ongoing regulatory, fiscal, operational, and personnel oversight.

The size of the CCRM (1,600 studies with 250 principal investigators and 219 research staff across 22 departments, centers, and institutes) has provided the ability to disseminate information quickly and broadly. At the pandemic's onset, COVID-19 research was prioritized while other ongoing and new non-COVID-19 studies were temporarily halted. Importantly, the CCRM's infrastructure fostered movement out of individual research silos into collaborative research groups, as well as connected multiple stakeholders who brought several types of expertise together to address the research questions generated by the pandemic.

The utilization of existing centralized research infrastructure has offset challenges that would have been inherent to decentralization of activities, including effort redundancy, miscommunication, and lack of cohesive research strategy. The centralized oversight has also allowed for ease in administration as over time non-COVID-19 research, placed on hold at many AMCs, has largely restarted and continues amid the ongoing pandemic.

Establish COVID-19 Research Policy

The pandemic response has been unprecedented with investigators from all areas of medicine, not simply virology and infectious disease, designing projects to understand, treat, and prevent COVID-19.^{5} Many investigators initially lacked experience in conducting research in an environment where the patients, staff, and scientists are at risk through even the simplest of in-person interactions, where biospecimens present significant and often unknown risks, and where personal protective equipment (PPE) has been in short supply and, at times, appropriated by the clinical mission.

In response to managing these risks, a comprehensive research policy was implemented through the College of Medicine, with oversight by the CCRM, to identify and guide investigators seeking to engage in COVID-19 research. This policy has required investigators to complete an impact and planning assessment for any COVID-19 research (e.g., laboratory-based, biorepository, observational, interventional, and therapeutic). The assessment includes those factors identified as most important by research and medical leaders as to whether to engage in a proposed research study: impact on healthcare and research team safety, PPE resources needed, ability to implement regulatory and biosafety safeguards, scientific merit, and funding status.

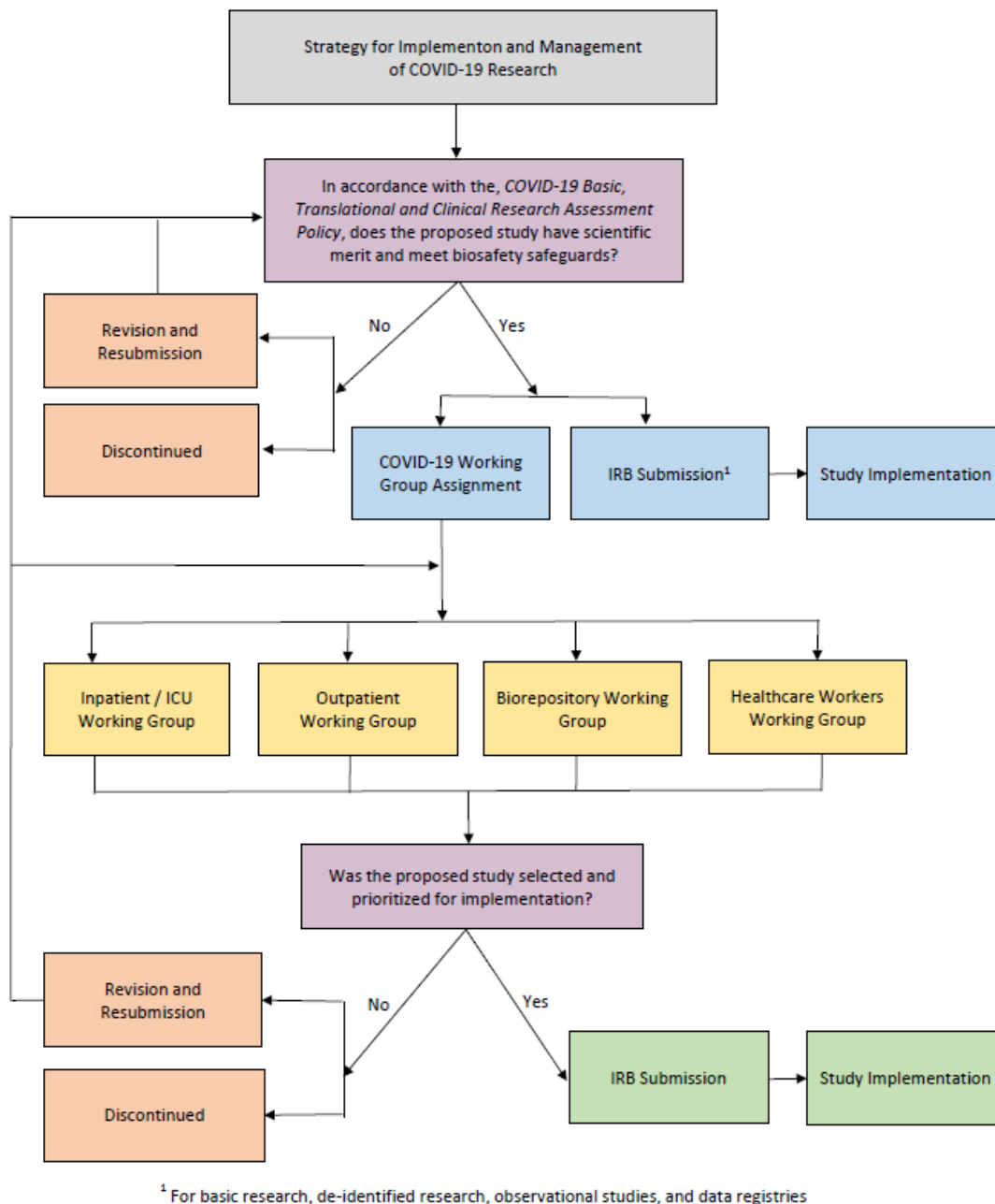
In practice, assessment approval has been required prior to seeking institutional review board (IRB) approval for COVID-19 studies or modification of existing studies adding COVID-19-related aims. Figure 2 (next page) illustrates the strategy for managing COVID-19 research. The policy with its associated review process has been successful in the identification, tracking, and management of our AMC's COVID-19 research response (215 assessments received; 145 approved to move forward, e.g., IRB submission as applicable).

Create Multidisciplinary Research Working Groups

In response to the pandemic and the call for clinical research, four multidisciplinary coronavirus-centric working groups (e.g., inpatient/intensive care, outpatient, biorepository, and healthcare workers) were created and have served as another means of organizing the research response. These working groups consisting of investigators and clinical research personnel from differing disciplines, have been responsible for driving study feasibility (reviewing 90 proposals and opening 43 studies to date), making final recommendations for study selection and prioritization, and reporting progress and associated obstacles to the centralized research leadership (CCRM).

Study selection and prioritization was based on those studies deemed as contributing data to the larger understanding and treatment of the COVID-19 virus and were consistent with investigator interest/knowledge, patient availability for enrollment, and resources (e.g., personnel, equipment). The working groups have also helped with early identification of ineffective investigational therapies enabling prompt operational pivots to subsequent studies in the queue.

Figure 2: Strategy for Implementation and Management of COVID-19 Research



Additionally, studies are grouped and prioritized by intervention type to limit those with overlapping mechanisms of action. Study categorization has improved selection efficiency and allowed for the development of a diverse portfolio of COVID-19 studies that improve patient care by providing treatment options. Whenever possible, research protocol requirements have been aligned to standard of care/daily care practices to manage added work for practitioners.

The working group model, further illustrated in Figure 2, has provided a structure that fosters consensus building across disciplines in the selection and implementation of studies that show the most promise for treating patients, as well as contributing to scientific knowledge (the two highest priorities for study selection). Currently, these working groups have remained in place to continue guiding study selection and prioritization regarding treatments and the long-term impacts of the SARS-CoV-2 virus.

Connect Institutional Research Stakeholders

Increased institutional connectivity and regular review and interpretation of COVID-19 guidelines have been conducted communally amongst Ohio State research stakeholders (e.g., CCRM, Center for Clinical and Translational Science (CCTS), disease-based research units, IRBs, sponsored programs, compliance offices) to ensure clarity and ease of implementation.{6} Throughout the pandemic, guidelines reviewed have included definitions of essential versus non-essential research, cessation of in-person research visits, increased use of telemedicine, transition to telework, and utilization of touchless consenting practices.

For those investigators and research staff involved in consenting COVID-19 patients into studies, a weekly call was initially established to review updates to guidelines and research processes specifically related to e-consenting, documentation, and screening. This has helped to establish common practices and maintain regulatory compliance standards (see Table 1 on next page for a summary of workflow adjustments and policy changes that have been related to COVID-19). These research-related adjustments remain pertinent to ongoing research operations as the pandemic continues and COVID-19 studies have largely transitioned from emergency use studies to randomized clinical trials and, more recently, into long-term outcome studies.{7}

Additionally, communication between the centralized research infrastructure (CCRM) and the CCTS has contributed to the alignment of institutional COVID-19 research priorities with national initiatives to combat the pandemic. The Network Capacity Program of the CCTS has identified opportunities to participate in COVID-19 clinical and translational research studies supported through national and regional collaborative networks. This communication has allowed the CCRM to engage in prompt dissemination of interest to the appropriate

investigator(s) and their respective disease teams as they are readily identifiable. This, in turn, has allowed for timely responses to research inquiries and site questionnaires, and for timely initiation of study startup activities.

Table 1: Clinical Research Workflow Adjustments and Policy Changes Related to COVID-19

PERSONNEL	CONSENT PROCESS	RESEARCH CONDUCT	RESEARCH DESIGN
Use of PPE (limit use to essential and/or COVID-19 research)	Submission of remote/distance consent discussion processes with initial IRB applications	Utilization of telemedicine for study visits	Alignment of study procedures with standard of care to limit staff exposure
Transition to telework (ensure staff had compliant and adequate technology)	Application of eSignature platforms for obtaining subject/Legally Authorized Representative signatures	Utilization of home healthcare to obtain key safety data (labs, ECG, etc.)	Execution of adaptive protocol design
Formation of interdisciplinary teams of coordinators	Utilization of electronic communication platform for facilitating consent process (discussion and signatures)	Increased use of remote monitoring of data	Engagement with IRB to include vulnerable populations (prisoners, pregnant women)
Implementation of weekly virtual meetings with COVID-19 research staff to improve efficiency and recruitment		Application of eSignature platforms for obtaining regulatory document signatures	
		Enhancement of remote investigational product distribution	

The overall benefit of connectivity to stakeholders has been even more clearly manifested throughout the pandemic, as our evolving understanding of the nature of the virus and the associated guidances have significant consequences for all members of the clinical and scientific community. Swift implementation of large-scale COVID-19 practices has required numerous successive and parallel operations on every level of the AMC, thereby showcasing collaboration and institutional connectivity.

Conclusions

Along with illustrating the pandemic's initial and ongoing impacts on the AMC research landscape at The Ohio State University Medical Center, this article has highlighted best practices for navigating these impacts. The key strategies of utilizing and extending existing research infrastructure, establishing common policies, implementing identifiable leadership through multidisciplinary working groups, and driving increased connectivity and consensus building among stakeholders has placed this AMC in the best position possible to handle the challenges as the pandemic initially developed, worsened, and now continues to evolve into waxing and waning episodes.

These best practices, born out of necessity, highlight how quickly effective research management changes can be created and implemented and serve as a guidance for other AMCs as well as other groups engaged in clinical research. Importantly, the processes successfully mobilized to ensure adaptability and consistency in clinical research operations have remained in place throughout the ongoing pandemic in order to continue effective and responsive clinical research management.

The lasting impact of COVID-19 on research-specific processes (e.g., use of eConsent, offsite monitoring) will also continue to evolve along with the pandemic, as the need for advancements in research will coexist with the need for effective clinical management of the COVID-19 illness.

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PEER REVIEWED

Opinion: More Sites, Sponsors, and CROs Should Leverage eSource as a Study Manager in Remote Monitoring Situations

Takoda H. Roland, CCRA, CCRP, CNA



I have long been a proponent of the potential of electronic source documentation (eSource) and its advantages in clinical trials. From my experience as a clinical research associate (CRA), I wrote about eSource several times^{1,2} in a period when I had come to see that clinical research was only just scratching the surface on leveraging the technology to fundamentally change the way we monitor clinical trials.

At the time, I did not expect to find myself in a position to make a meaningful shift toward remote monitoring. Several years later, while working as a clinical team manager on a global pivotal Phase III study for an Investigational New Drug application, COVID-19 forced contract research organizations (CROs) to rethink their monitoring paradigm. Drawing from both my own and my team's experience with a leading provider of eSource services, our study was able to successfully implement a remote monitoring process to mitigate the issues of running the trial during the pandemic. Even as someone who had long advocated for remote monitoring using eSource, I found myself astounded at the success our team achieved.

Despite the myriad additional issues caused by COVID-19, our study team's efficiency dramatically increased with remote monitoring.

As a CRA in 2018, I was fortunate to come across several research sites that were early adopters of eSource and to see how its benefits were immediately evident. Switching to eSource dramatically reduced the workload for sites by streamlining their entire documentation process.

The improved efficiencies in data entry vs. handwritten notes, along with a clear step-by-step process for each specific visit, reduced patient visit times.

Leveraging eSource also delivered a significant reduction in errors and missed procedures at sites thanks to real-time data validation. When I did find errors, the audit logs and queries directly on the eSource page were considerably easier to close than the traditional pile of sticky notes monitors are accustomed to utilizing.

One of the inefficiencies I previously noted in earlier publications is the lack of standardization in site sources. Too much time is spent as a CRA familiarizing yourself with each site's specific source. Due to every site creating a unique source, it is not uncommon for critical datapoints to go uncaptured in the beginning of a study. Standardization of the initial source would reduce the workload of both sites and CRAs, while ensuring critical datapoints are not missed and increasing the chances of noticing trends across sites. With robust eSource tools in play, standardization makes study management and version control in protocol amendment situations much easier, as well. eSource also allows the CRA to spot check the site's source remotely to ensure it captures all required visits prior to the first patient's visit.

I have seen firsthand how sites can leverage eSource in several surprising ways. Some sites indicate that using eSource allows them to work with more doctors and in different therapeutic areas that they had previously been unable to find help with. With the ability for principal investigators (PIs) and sub-investigators to review patients charts as eSource from their private practices or homes, the burden on doctors is greatly reduced. For example, investigators' review times for adverse events are reduced since they no longer need to physically travel to the research office to access charts. One site I encountered even outsourced electronic data capture entry of its source to an offsite facility in a different state.

While eSource offers many advantages to research sites, I believe it benefits sponsors and CROs even more.

To unlock the full potential of eSource by enabling remote monitoring, a study needs the buy-in of both the CRO and sponsor. I had been pushing several years at my CRO to try to implement remote monitoring leveraging eSource to no avail. Then, everything changed when COVID-19

shut down onsite monitoring. Remote monitoring was no longer just an idea or small add-on, it was something we needed immediately and should have started implementing years ago. Flights were getting cancelled, CROs grounded CRAs, and sites decided the last people they wanted to see during a pandemic were CRAs who had travelled through multiple major airports that week.

As soon as the impact of COVID became evident, I started working with our study team and sponsor toward potential solutions. Reaching out to our study sites, we identified several sites that were already using eSource for tasks tied to such areas as their clinical trial management systems (CTMSs), payments, patient recruiting efforts, electronic regulatory needs, and more. Sites that had standardized their eSource practices were able to continue recruiting patients and running trials with minimal to no interruptions. This was not the case for sites that had not made the switch to eSource.

Our team pulled in resources from data management, the sponsor, sites, and our clinical team to amend our study monitoring plan to allow for remote monitoring visits, resulting in improved monitoring metrics across the board.

While other study teams were stuck at the mercy of COVID-19 restrictions, our team achieved some of our highest metrics. Our company's expectation is around the industry average for days on site (DOS), requiring CRAs to perform in-person onsite monitoring at a research site eight to 10 days per month. However, virtually every study struggled to have CRAs meet their DOS metrics as sites were closed. Even once sites reopened to allow CRAs, the backlog from other studies caused a ton of intra-study competition for space on site for monitors.

Many research sites had additional staffing issues related to cutbacks from COVID-19 that further exacerbated the issue of getting monitoring time onsite. With the implementation of remote monitoring, our CRAs exceeded their traditional DOS metrics, resulting in more pages monitored, improved patient safety due to the reduction of monitoring lag times, and improved CRA efficiency from no longer losing valuable time to travel.

After a few successful trial remote monitoring visits using our favored eSource tool, the study team started to reach out to more sites to see if there were any others using potential eSource solutions. We identified two sites that were using a particular CTMS in this manner. While it did

seem to have the potential to be used as an eSource that was compliant with the expectations of the *Code of Federal Regulations* (CFR) Part 11, we met with mixed results using it. One site was successfully using it in a way that met industry standards for source data capture, however our CRA's page monitoring rates there were a bit lower than at sites using the eSource our company favored. The other site was using that same CTMS in a way that was not CFR Part 11-compliant, and this continued to be an issue throughout the study.

We had several sites implement eSource mid-study as a COVID-19 mitigation with mixed results. While implementing eSource mid-study did allow us to complete remote monitoring for new study information, it remained a challenge to verify source data for earlier visits. Some coordinators reported that learning a new system mid-study was an additional burden under already-stressful conditions.

Ideally, an eSource solution is implemented prior to study start. While eSource has great potential, it is critical that due diligence is being done when selecting a vendor and that there is a defined plan to ensure successful implementation.

On our study, we also utilized a hybrid model for monitoring support. Our monitors would attempt to achieve their full DOS expectations at their dedicated sites, however logistics challenges related to COVID-19 made this impossible. Last-minute cancellations due to new policies, COVID-19 outbreaks at sites, flight cancellations, and site closures often left our monitors without scheduled DOS.

Sites with eSource can accommodate many monitors with much shorter notice since they do not need to plan for physical space for the monitors. Monitors onsite are more disruptive to a study coordinator who likely has patients to see. With eSource queries, study coordinators were willing and able to accommodate last-minute visits and address study findings without the visit disrupting their schedules.

Beyond the obvious increase in DOS that we were able to achieve with our monitors not losing time to travel, our study team also saw an increase in the number of pages monitored per day with the remote model.

Our monitors gained access to study data more quickly without the restriction of planning onsite visits. Early access to data meant errors were captured more quickly and corrective actions implemented faster. With corrective actions in place, our sites participating in the remote monitoring saw fewer errors overall.

Further, study timelines were much more easily managed for our sites participating in remote monitoring. Last-minute visits were no trouble to schedule for our sites enrolling their first patient, allowing our study team to meet our monitoring plan requirement of monitoring the first patient within two weeks of enrollment. Meeting schedules for data management batch-cleaning and achieving goals for database locks were also easy for our team with remote monitoring, due to reduced friction in timelines. Medical review timelines were met with remote monitoring access to data, cutting out the traditional middleman between the PI and medical monitor.

Our study team members were more efficient when monitoring with multiple screens from the comfort of their home offices as opposed to being crammed in a makeshift monitoring room. This change in the monitoring workflow resulted in improved CRA retention, as many studies had CRAs leaving the clinical trials industry completely. Even from our less tech-savvy monitors, the feedback was unanimous:

Remote monitoring was preferred due to lifestyle comfort, efficiency in monitoring, and ease of scheduling.

Our CRAs were happy to increase their monthly DOS from the expected eight to 10 to as high as 12 to 16 when it meant not having to endure long hours at airports away from their families. Our study was so successful due to our implementation of remote monitoring, that our study alone accounted for more than 25% of the company's third-quarter revenue.

The study greatly exceeded revenue expectations despite the pandemic, all thanks to our implementation of remote monitoring.

Our study implemented remote monitoring as a COVID-19 mitigation. While I was excited to finally leverage eSource to enable remote monitoring, it is disappointing that it took a global pandemic for the clinical research enterprise to finally wake up to the 21st century. Remote

monitoring should be the integral component of every clinical trial. With remote access to source study data, the model of dedicating an entire DOS to one specific site will change.

Specific visits like those for first enrollment and pages like those for adverse events can be prioritized study-wide for monitors to add the most value toward the study and improve patient safety.

Continuous monitoring breaks the traditional monitoring cycle. Trip reports are based on the frequency at which monitors can get onsite and are not always an accurate representation of the amount of work being performed at a given site. Continuous monitoring allows for regular reports for individual sites to be run and written at scheduled intervals to improve their value. Regular reporting across all sites also allows for easy site-to-site comparisons. Performing such comparisons makes it easy for study teams to identify high-risk sites and allows for true risk-based monitoring, which calls for clear action when risks are identified.

When remote monitoring is the standard, onsite monitoring serves as an excellent tool to mitigate risks identified in site risk reviews.

While our study team was able to prove many of the benefits of eSource not just for sites, but also for the CRO and sponsor, I'll wrap up with the same message I started with:

We have still only scratched the surface of how eSource will change monitoring in clinical trials.

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PEER REVIEWED

Navigating Through an Academic Capstone Project in the Time of COVID-19

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Clinical research workforce development efforts require a focus on the education and training of clinical research professionals who ensure the quality of study performance to improve the public's health and instill trust in the outcomes of these studies. Academic research medical institutions are charged with the development of this educational pipeline along with the academic and career continuum. Graduate research education is a crucial step in the pursuit of crafting educational programs that will

best prepare young scientists and biopharma industry professionals for careers in clinical and translational research.{ 1 } A final “capstone” project within a master's program can improve upon a curriculum that successfully meets the advanced level competencies.{ 2 }

Formal academic clinical research degrees based on comprehensive competencies provide students a sense of security of being trained. Additionally, adherence to the Joint Task Force (JTF) Clinical Research Professional Competency Framework promotes the minimum standards required for accreditation of such degrees intended to enhance the quality of education of clinical research professionals.{ 3 }

This article focuses on how one graduate school's MS Clinical Research Management program includes a capstone project which involves a final presentation, poster, or manuscript on a topic based on concepts learned throughout the program. The project is tracked through a project plan that contains timelines, deliverables, and anticipated risks, as well as its proposed mitigations, methodology for implementation, and projected outcomes. The capstone project deliberately targets principles of leadership and professionalism encompassing communications and teamwork skills necessary to successfully conduct clinical trials as outlined in Domains 7 (Leadership and Professionalism) and 8 (Communication and Teamwork) of the JTF Competency Framework.{4}

The COVID-19 pandemic resulted in a considerable barrier for students' ability to implement their capstone projects under normal processes. Barriers that relate to leadership, professionalism, communication, and teamwork presented significant challenges. Two students (Student 1 and Student 2) projected to complete their capstone project in 2020 at their respective companies were precluded from implementing their projects onsite due to complete lockdown and strict quarantine rules related to COVID-19. Such a challenge required the instant application of advanced level of communication, leadership, and professionalism to successfully complete a project in the uncharted environment of the virtual space.

The objective of this paper is to track the journey of these students who were faced with the burden of having to readjust their capstone project activities while in lockdown at the height of the COVID-19 pandemic, by highlighting the tools they used to cope with the rigors of meeting the project deliverables.

Methods

Student 1 was required to fulfill the following obligations to meet their capstone project: 1) create a mapping tool for real-world evidence (RWE) by accessing proprietary databases through a company's secure portal, 2) create a checklist of data-cleaning rules/points for an RWE database, and 3) collaborate and participate with the company's in-house RWE team on insight generation activities that will align with the mapping tool.

While parameters and tasks were initially set before COVID-19 hit that would have allowed face-to-face engagement with relevant stakeholders and onsite access to proprietary databases, Student 1 adjusted the project plan by setting up the tasks to be performed remotely. Bi-weekly calls with the faculty content advisor and weekly virtual meetings with the company preceptor were immediately initiated even before the official start date of the capstone project.

Student 1 needed to get approval for the project adjustments and sought assistance for additional accommodation on submitting deliverables. Timelines for deliverables were reset, and a table of constraints with projected mitigation techniques was implemented. A communication plan was established for scheduled virtual meetings with multiple stakeholders from the RWE team, which had to adjust its own projects involving healthcare providers from whom the insights needed by Student 1 were going to be generated. Student 1 had to ensure a continuous flow of information to complete the project requirements despite the limited access to both the stakeholders and the databases.

The capstone project for Student 2 required the following obligations: 1) assessing the impact of COVID-19 on Medical Affairs' activities of insight generation, stakeholder engagement, and scientific exchange at a specific company, 2) revamping the roles and responsibilities of the company's medical science liaisons to adapt to the shift caused by the pandemic,{5} and 3) developing an innovative system for stakeholder engagement.

Student 2 adjusted project timelines and deliverables based on securing regular virtual meetings with relevant company decision makers who were also on lockdown with limited access to the company's secure portal. Weekly meetings with both the preceptor and faculty adviser were conducted as information from both public and private sources were being collected.

Student 2 escalated issues to company executives as needed by the project, especially when facing opposition due to the company also being on lockdown with heightened internet security checks that it was not prepared to endure with all of its employees working remotely. The project included developing an innovative program of activities needed to be performed virtually to keep the community of clinical stakeholders aligned with the company's products.

For 15 weeks, the only means of communication and delivery of the work done by Student 1 and Student 2 were via the school's learning management system, e-mails, video conference calling, and telephone. Apart from discussions about each of their project's status, each student was queried on the status of their health, home life, and overall mental state as the COVID-19 pandemic worsened throughout 2020 and global conditions such as the economy, emotional state, family life, and overall well-being were hampered.

Reliance on technology, close collaboration with both their preceptors and faculty advisor, and resilience in facing ongoing challenges to ensure project completion were attributes each student needed to develop overnight. The final deliverable for both students was a live online presentation to the program faculty, other students, company preceptors, and colleagues.

Results

Student 1's project necessitated having access to a company's proprietary databases as well as third-party databases to be able to implement the project plan. Based in Beijing, China, they were quarantined at home and therefore had no access to the company databases needed for the project, as the Chinese government had imposed stringent lockdown rules.

This capstone project ran at the onset of the pandemic, from January to April of 2020. During this time, Student 1 was faced with not only mitigating the constraints related to accessing databases, but also constraints at home which included homeschooling children, caring for an elder, and having limited access to food and other necessities. By the time the project was completed, it was April 2020 followed by a virtual graduation in May 2020.

Table of Constraints—Student 1

Objective	Constraint (Risk)	Impact	Mitigation (Contingency)
Objective 1: Creation of mapping tool for real-world databases in China	Poor accessibility of the information from the databases in China.	High	1. Obtain the preceptor's help by using company resources to gain more information. 2. Avoid using databases with limited information.

Objective 2: Creation of a checklist of data-cleaning rules/points for an RWE database	<p>1. Timeline may change for the project depending on the RWE team's planning for 2020.</p> <p>2. Large amount of data and nonstandardized variables of the database will increase the workload.</p>	Medium	<p>1. Closely follow up with mentor and preceptor for adjustments to be made in terms of choice of databases to be evaluated and/or adjustments to projected outcomes from the project.</p> <p>2. Closely check project plan timelines and deliverables.</p> <p>3. Gather information related to RWE databases, identify barriers to access/develop processes to support a better structured database to house relevant information for the project.</p>
Objective 3: Align with the RWE team	<p>1. Due to the outbreak of COVID-19 in China, travel restrictions and strict quarantine rules delayed the start of the project.</p> <p>2. Project shifted from onsite to remote from home due to the severe restrictions posed by the COVID-19 outbreak. This may prevent the student from participating in meetings and activities with the RWE team in terms of generating materials and access to databases needed for the project.</p> <p>3. Student needs to continue to work fulltime, manage family duties, and deal with other personal responsibilities under strict quarantine rules.</p>	High	<p>1. Schedule online meeting with preceptor and advisor earlier while closely monitoring status of the COVID-19 outbreak.</p> <p>2. Plan with the student's direct supervisor and apply flexible working hours to accommodate time for project execution remotely.</p> <p>3. Closely monitor project timelines, along with current regular workload deliverables while keeping a flexible schedule to accommodate duties at home.</p>

Student 2 had been working as a medical science liaison and subsequently took on a leadership role within the Medical Affairs team of a global rare-disease biotechnology company in the U.S. For a rare disease company, the risks are greater with the burden of delivery resting mostly on the shoulders of medical science liaisons.

Student 2's project was conceived at the height of the COVID-19 pandemic{6} in the U.S. and they had no option but to push through with a capstone project, as it was the only course left required for completion to graduate. Due to a complete lockdown, Student 2 had to find alternative ways of interacting with needed stakeholders for the project; their team became compromised with the unfortunate loss of personnel due to company cost cutting. Further, Student 2 had to take on more responsibilities while implementing the tasks needed to complete the project.

One-on-one engagement with the company stakeholders and access to confidential documents while maintaining strict privacy rules—as per the company's standard operating procedures (SOPs)—were needed to assess the impact of COVID-19 on the function of medical science liaisons. Identification of potential risks to any proposed changes in the process of engagement with physicians and healthcare providers had to be incorporated into the execution of the capstone project plan.

Table of Constraints—Student 2

Objective	Constraint (Risk)	Impact	Mitigation (Contingency)
Objective 1: Assess pre-, current, and future COVID-19 impact to the Medical Affairs industry{7}	Limited and/or no literature to address capstone objective.	High	Will seek to conduct survey with small sample size to consenting physicians with whom the student has a working relationship. Survey limitations: small sample size, limited reach of different clinician disciplines, and time.
Objective 2: Redefine Medical Affairs field role and metrics	Lack of published competitive data for physician engagement benchmarking.	Medium	Will explore other data sources for this information with preceptor and course advisor.

Objective 3: Design an innovative engagement proof of concept	1. Company may not have the internal assets to accommodate engagement concept and mobilization.	Medium	Summarize the resources needed and associated cost benefit analysis to acquire needed assets (tools, capabilities, platforms).
	2. Proposal review/scheduled meeting/approval of concept	High	Present plan and mobilization plan in final capstone presentation and events that delayed milestones.
	3. Mobilization of proof of concept		

The assigned faculty content advisor and company preceptors provided guidance. They mentored both students through the implementation of their projects while themselves being quarantined. The detailed project plan, along with the tables of constraints, provided the best structure for each student to perform successfully (see Table of Constraints—Student 1 and Table of Constraints—Student 2).

Bi-weekly meetings were alternately set between each student, their preceptor, and the faculty content advisor. During these video meetings, discussions revolved around the project status, including identified constraints and how they were managed. It afforded a platform for the student to report on their progress with project deliverables, as well as to share insights regarding their physical well-being and mental health.

The establishment of a secure environment for honest exchange became a catalyst for the students to persevere despite the limitations posed by the pandemic. The situation also subjected their resilience to a rigid test of wits that drove them to become more creative and nimbler in gathering the information they needed to fulfill their deliverables, despite revised company security and privacy SOPs. While both expressed a form of “videoconference fatigue,” having the ability to speak with someone via a virtual platform where they heard another person experiencing similar constraints provided the much-needed balance each student sought as a means to detach from “lockdown fatigue.”

Both students experienced considerable amounts of stress which impacted their mental health. {8} During weekly video conferences, both students candidly included in their discussions details of how they worked on project activities and simultaneously dealt with the accompanying challenges that impacted their thought processes and sleep and eating habits. They soon realized the need to become more astute at devising ways to cope with multitasking between being a parent, spouse, employee, and student. Both noted how they started using the quiet times in the late evening, when everyone else in their household was asleep, to focus on their schoolwork and decompress from the daily grind.

Ultimately, Student 1 and Student 2 completed each of their capstone projects despite much trepidation. Each one delivered well-conceived presentations that garnered high approvals from preceptors, advisors, the capstone director, and the program director.

Discussion

Both students were able to successfully complete their capstone projects because of their well-developed project plans. The plans each consisted of a rationale, objectives, timeline and deliverables, and risk mitigation. Along with their plan, each student was provided a preceptor and a faculty content advisor. The integration of the preceptor and content advisor for the provision of real-time guidance played a significant role in the success of the capstone project during the unprecedented circumstances brought about by the COVID-19 pandemic.

To successfully navigate a capstone project in conditions ranging anywhere from stable to disruptive, students need to embrace the combination of their plans with their connections to committed and engaged preceptors and advisors. This combination enabled the plan to serve as a living document that was flexible enough to align with whatever tools and services were available to the student. This process resulted in meeting the requirements of JTF Competency Domains 7 (Leadership and Professionalism) and 8 (Communication and Teamwork), and added to the overall desired outcome of the MS Clinical Research Management program.

The communication process kept all stakeholders resilient and focused on the team's efforts. Engagement among the stakeholders that was frank, open, and reassuring kept each capstone project viable. Despite the potential for negative effects to students' mental health due to anxiety and stress levels compromised by the uncertainty of the pandemic, it was the realization of the project's completion that became the light at the end of the tunnel.

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FORM & FUNCTION

A Hybrid Approach to Decentralized Trials

Scott Gray



Though the concept has existed for quite some time, the emergence of COVID-19 thrust decentralized trials (DCTs) into the mainstream. Practically overnight, quarantines, site closures, travel restrictions, and the health risks of the virus itself drove clinical trials across the globe to a screeching halt. Clinical research organizations (CROs) and pharmaceutical study sponsors were uncertain about how to move forward while keeping their patients safe.

As the pandemic spread, life science organizations pivoted to technology to continue data collection and engage with patients. In a global survey of companies involved in clinical trials, the vast majority of respondents agreed COVID-19 [accelerated the adoption](#) of DCTs within their organizations. Ready or not, this real-world test allowed the industry to continue its studies in the face of unprecedented disruption.

Decentralized Trials: Here to Stay

DCTs leverage wearable medical devices, telemedicine, home visits, and local healthcare providers and laboratories in place of visits to traditional study sites, such as large academic medical centers, to manage drug administration and data collection. These solutions come with many potential benefits, such as better data quality and a more convenient experience for the patient. In many cases, they assist in shortening the time it takes to get new drug treatments to market.

For example, wearable devices offer near real-time patient data compiled in real-world scenarios as patients go about their daily lives. Using the same instruments and processes to collect data among participants reduces inconsistencies and streamlines the researchers' data analysis. These devices also eliminate the need for patients to travel to central trial site locations, making it easier to participate by reducing the costs and logistical barriers which derail enrollment and retention. Engaging patient populations who otherwise might be unable to participate due to financial, geographic, or other personal constraints could, in turn, have a positive impact on increasing [patient diversity](#).

Recognizing the challenges presented by COVID-19 and the growing prevalence of DCTs, the U.S. Food and Drug Administration (FDA) issued [guidelines for conducting trials during the pandemic](#) to help protect patient safety while minimizing risks to trial data integrity. For the first time, these guidelines provided CROs and trial teams with a regulatory perspective and suggested protocols for implementing remote patient care. These recommendations supplied guidance for conducting patient visits by phone and video conference, dispensing investigational treatments for self-administration at home, managing lab and imaging needs for patients, and detailing how remote efforts might impact study protocols.

Given their advantages and the new thinking provided by organizations like the FDA, it is safe to assume the use of DCTs will only continue to grow. However, this trial method's quick adoption also revealed many shortcomings. Though some challenges will be naturally mitigated as the DCT process matures, others have demonstrated why DCTs will never be a one-size-fits-all solution for patients and clinical trial teams.

Where Decentralized Trials Fall Short

Historically, clinical research teams have stored patient information in secure data management systems. By increasing the number of data collection methods used in a given study, DCTs can run into compatibility and consistency issues, making it difficult to reconcile data and security issues and creating risks to patient privacy.

The same technology enabling DCTs to succeed can also contribute to their downfall. Wearables and monitoring devices, for example, require patients to have access to reliable internet

connectivity and the ability and desire to learn to use them as they are intended. Virtual participation may not be an option for patients unfamiliar with technology or those living in rural or poverty-stricken areas. Thus, inclusion criteria requiring participants to use smartphones and apps could unintentionally hinder patient diversity. Likewise, factors related to reliance on self-reporting and long-term adherence to these collection methods prompt the question of data accuracy, which could raise alarms among review boards and regulatory bodies.

Further, trials for patients with rare diseases are often too complicated for a DCT approach. Self-reporting and home visits are not always feasible for these patients and their [caregivers](#). Many rare disease patients prefer the reassurance of meeting with specialized staff to address their complex medical concerns. Decentralized trials are not designed to offer the high-touch support these patients and their caregivers often require.

Additionally, due to the nature of rare disease patient populations, researchers and sponsors must often enroll patients from multiple locations across the world. With each new country comes an additional set of regulatory requirements for collecting and sharing patient data and the potential of language barriers and cultural nuances impacting communication. In many cases, having patient support staff from the same regions and countries as patients is the most efficient way to ensure trials proceed as planned.

A Hybrid Approach to Trial Design

A study conducted in 2021 found [insufficient evidence](#) to confirm which trial methods are most effective in terms of recruitment, retention, and cost. Despite the potential advantages of DCTs, brick-and-mortar trial sites remain a critical component, as a decentralized approach cannot apply to every clinical trial. As travel restrictions and public health risks ease, and we embrace a return to normalcy, adding DCTs to our collective toolbox is a strategic move, as is learning to select the right tool for the job.

In many cases, combining the personal care provided by traditional clinical trials with patient-centric elements of DCTs will be the most effective solution for study design. A study published by the American College of Cardiology found that clinical trials for drug approval often include

[decentralized elements](#). DCTs tend to incorporate aspects of traditional trial design with decentralization of the patient/medical staff interactions.

For clinical trials focusing on rare diseases, a hybrid (onsite/offsite) approach could offer the convenience of home care and telemedicine to reduce the number of in-person site visits while administering complex treatments in the safety of a controlled clinical setting. This hybrid application of the protocol would make the overall travel commitment more manageable throughout multi-year studies, reducing the burdens placed on patients and their caregivers.

Conclusion

Moving forward, we must continue to assess the value provided by DCTs in ensuring patient experience and safety remain of the utmost priority. We should continue to build upon what has been learned since the onset of the pandemic. It is up to clinical trial stakeholders to determine the best approach for balancing the needs of patients and their caregivers against the goals of CROs and pharmaceutical study sponsors. Whether that means a decentralized, traditional, or hybrid course, prioritizing clinical trial patients' health and best interests ultimately encourages higher enrollment, increased retention, and more robust data collection results.



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GOOD MANAGEMENT PRACTICE

DCTs: Key Considerations for Small-to-Midsized Biotechnology and Biopharmaceutical Companies

Kristin Mauri



Decentralized clinical trials (DCTs) are no fad; they are entrenched in the future of clinical development. That is good news for patients with obvious advantages, but the trend may seem daunting for small-to-midsized biotechnology and biopharmaceutical companies.

Indeed, smaller companies may not even consider DCTs, feeling that the risks of treading this new territory—an area with complex data management demands and no clear regulatory guidance—outweigh the potential rewards. Many small and midsized biotech and biopharma companies feel that DCTs are outside their comfort zone and budgets. That is not necessarily true.

Fully Remote? Hybrid? What Exactly is a DCT, and Why Go to All That Trouble?

DCTs are known by many other names: virtual, remote, direct-to-patient, siteless, hub-and-spoke. Far from being 100% remote, they are typically hybrid (onsite/offsite), with a sliding scale of decentralization. Even when conducted by big pharma, DCTs combine onsite therapeutic interventions and testing with remote activities.

A DCT may involve a centralized site, with which patients engage via televisits augmented by remote monitoring. They may use local healthcare providers or optimized digital technologies.

For a small or midsized company, a DCT could be as simple as adding an electronic patient-reported outcome (ePRO) system to a study that wouldn't have previously included that.

The driver for a DCT is that it is inherently more patient-centric. By bringing the study to the patient, patients are more incentivized to participate; it is, quite simply, easier for them. That helps enrollment overall and helps sponsors increase trial diversity by making participation easier for people across geographies, ethnicities, and socioeconomic groups. So, based on recruitment alone, sponsors are wise to make some degree of DCT part of the solution. How much of the solution—determining where on the decentralized spectrum a trial should fall—is driven by factors such as the indication and product, the geography and trial population, and the study phase.

Myth-Busting: DCTs are Expensive, Giving Big Pharma a Natural Advantage

Because DCTs require more bandwidth, additional third-party vendors, and greater financial resources, many people believe that deep pockets give big pharma a built-in advantage in conducting them. The truth is different: DCTs have the potential to enjoy easier recruitment and provide long-term cost savings that may outpace the upfront investment required. Those savings come across the board, starting with the efficiencies gained by reducing the need for face-to-face interactions with patients; for example, the ability to conduct electronic informed consent with patients is an enormous time-saver. DCTs can also reduce trial times by one to three months, delivering substantial savings.

Further, there are additional cost reductions: Untethered from sites, DCTs can recruit from anywhere, which often leads to faster enrollment and fewer screening failures. That same geographic freedom also means fewer sites, thus fewer review boards, potentially lower regulatory costs, and greater flexibility around protocol amendments.

Coloring Inside the Lines: What Do the Regulatory Agencies Say?

Although aspects of DCTs have been gaining traction for years, their popularity exploded during the pandemic. To keep research moving ahead, regulators supported sponsors in pivoting to these

new trial models—but they failed to issue any specific guidance concerning the differences in data collection, monitoring, and analysis.

In December 2021, the U.S. Food and Drug Administration issued draft guidance on “Digital Health Technologies (DHTs) for Remote Data Acquisition in Clinical Investigations.” It addresses:

- Selection of DHTs that are suitable for use in the clinical investigation
- Verification and validation of DHTs for use in the clinical investigation
- Use of DHTs to collect data for trial endpoints
- Identification of risks associated with the use of DHTs during the clinical investigation
- Management of risks related to the use of DHTs in clinical investigations

Yet much of this guidance is related to the actual devices rather than the data the devices collect. In parallel, the International Council for Harmonization (ICH) is rewriting its guidance describing the responsibilities of all participants in conducting clinical trials. ICH E6(R3) Annex 2 will focus on nontraditional interventional clinical trials, such as DCTs. It is anticipated in the summer of 2023.

Without explicit guidance, some sponsors—especially small or midsize developers with no previous experience in DCTs—may feel they are taking a risk. Fortunately, the right technology, backed by a robust risk management strategy, can help effectively mitigate that risk.

From Traditional Trial to DCT: What Can You Adopt? What Needs to Change?

What are the key considerations for small-to-midsize biotech and biopharma companies that want to migrate to the fast-evolving DCT model? Four main areas bear examination: Master trial design, protocols and processes, budget, and vendor selection. To an extent, they are all interrelated.

In a traditional trial, patients go to investigators at trial sites; those investigators enter the data into electronic data capture (EDC) systems. In a DCT, the patients may be entering the data or using data-gathering devices themselves, leaving the sponsors to figure out how to integrate,

manage, and analyze the data. What technology will be used, guided by what processes, and at what cost?

First, sponsors should define what their model will look like; then, they can understand what they will need to run it. For example, will some data be gathered at trial sites or the local hospitals? How often? Will patients use remote monitoring devices and ePro devices? Or will the trial combine multiple forms of data collection? How broadly dispersed is the trial? Will visiting nurses or other non-trial healthcare providers have a role?

Armed with the answers to these questions, sponsors can determine whether their current standard operating procedures align with this new model and, if updates are required, who will decide them. One useful method to keep track of the answers is creating a data map with the protocol development. The map outlines how the data are collected, the mechanism for collection, how it relates to other data, and how data will be monitored and cleaned.

Staffing comes into play, as well. Big pharma has ample people to manage various data sources and vendors. Small-to-midsized sponsors, by definition, lack those large staffing resources—but the solution isn't necessarily to hire a contract research organization (CRO) with a large staff and complex bureaucracies. Instead, these sponsors must identify a flexible and agile CRO whose remote technology patient engagement strategies incorporate the kind of automation on which DCTs thrive.

Logistics also play a role. In a traditional study, a therapeutic is delivered to a site's pharmacy, and that pharmacy distributes it to the patients when they come in for their visits. A research coordinator counts the remaining pills on a return visit to assess compliance. In a DCT, the drug can be delivered directly to the patient. Who will provide patient pharmacy support? How can the sponsor be sure the drug is delivered on time? How will they track compliance? Similarly, if a visiting nurse must be deployed to perform a test, how can a sponsor coordinate that data collection across geographies?

Budgetary questions weave throughout these issues—those tied to staffing costs, partnerships, shipping, call centers, and visiting nurses, for example. Yet, in considering the budget, small-to-midsized sponsors should remember the analogous cost savings that DCTs can deliver and include those in their overall budget calculations.

Finally, each of these factors—protocols, staffing, logistics, and budget—affect vendor selection. For many small-to-midsized innovators, this may feel like the biggest hurdle in adopting a DCT.

Vendor Selection: Which Technology Will Gather the Right Data?

Collecting data across multiple third-party systems can make DCTs exceedingly complicated—and potentially expensive. Sponsors need to understand what format the data are being collected in and delivered, and how they will get the data from the vendor; when multiple systems are in play, complexity increases—especially if vendors insist that all the data remain in their system.

Smaller sponsors grappling with this—especially for the first time—may want to invest in a consultant to help them sort through all their options. They may also want to consider a system-agnostic platform that aggregates data from any source, enabling them to work within a single operating system. This frees them to choose the optimal vendor for each aspect of the study while knowing that their data will always be centralized, with dashboards, workflows, and analytics that allow the sponsors to keep track of every aspect of the study. Such a platform offers seamless oversight that helps make even those sponsors new to DCTs feel confident in their ability to manage risk.

Dashboards, Triggers, and Workflows: Managing the Risk Around Uncertainty

In any trial, the bottom line is data. Are they complete? Are they clean? Are they high quality? Will they unequivocally prove the product’s safety and efficacy?

Risks associated with less than stellar data feel heightened when conducting a DCT. With data being patient-reported or uploaded from a wearable or other remote device, there is a constant concern that the patient may forget a report or the device may fail.

Again, small-to-midsized companies can mitigate such risks by using a platform with dashboards that offer real-time visibility into missing data. This ability to look at reports and status on dashboards that centralize, analyze, and track data and risks in real time and on an ongoing basis means that the sponsor’s size and resources become far less of a factor in the success of any DCT.

Navigating workflows in an integrated data management system eliminates the previous need in traditional clinical trials for slow, labor-intensive information analysis to detect key trends. Now machine-learning algorithms do that instantly—far better, far faster, far more accurately. Further, sponsors can establish triggers or workflows that show when data are out of range, when there's an anomaly and when something doesn't seem right. All this helps manage risk around uncertainty by significantly minimizing the uncertainty itself.

Centralizing the Data Mitigates the Risk of Decentralized Trials

Making the switch from a traditional trial to a DCT can be daunting. The processes need to change, people need different skill sets, and a host of new technologies are necessary. For small and mid-sized sponsors, particularly when integrating discrete data collection, analysis, and reporting methods, the prospect of managing vendors can be a considerable hurdle. Conversely, big pharma companies tend to power through these issues, finding ways to harness legacy data management systems that they invested in before DCTs exploded onto the scene.

The truth: Small and mid-sized sponsors have an advantage. They can leverage new data-source-agnostic management systems that integrate best practices while mixing and matching best-of-class vendors to optimize DCT results. That frees them to choose their technology at will, enabling them to minimize staffing, confirm logistics, and manage workflows. Critically, it also enables them to track safety risk, clinical risk, and operational risk in real time. That raises a sponsor's confidence in its ability to deliver patient safety, regulatory adherence, and clean data—thus minimizing the dangers that may be of greatest concern when first embarking on DCTs.

Such high-touch technology that automates data collection, interpretation, and reporting processes is much of what makes DCTs so attractive—not just because the data become more accessible, but because that accessibility is at the heart of DCTs' patient-centric allure.



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SITES & SPONSORS

The Ecosystem of Decentralized Clinical Trials: It Takes a Village to Modernize Care

MaryAnne Rizk, PhD



Creating new medications and medical devices is an enormous endeavor. Running a traditional, randomized controlled trials require millions of dollars and thousands of people to get it right. Now, as decentralized clinical trials (DCTs) become increasingly preferred, there are new spokes in the wheel (e.g., wearable devices, home-health nurses, systems integrators). Clinical trials, now more than ever, take a village.

We know that DCTs help improve trial speed, increase the number and diversity of participants, and collect better data. In fact, with the right tools, it's possible to screen 10,000 patients per day, enable 30,000 per month to schedule appointments, and provide remote or in-person visits to more than 180 sites worldwide. With electronic informed consent (eConsent), electronic patient recruitment, and direct-to-patient shipments, a decentralized workflow enables greater patient access while providing a flexible and seamless experience across all users that improves trial operations and time to treatment.

However, operationalizing DCTs often requires an ecosystem of partners. When a certified group of companies coordinate efforts to design and execute DCTs, sponsors, investigators, and patients benefit. A connected ecosystem of DCT collaborators can streamline operations and data collection, and resolve interoperability challenges. With a coordinated approach, the industry will accelerate this new model to make better medicines faster, safer, and more effective for every biology around the world.

Like-Minded Partners Maximize DCT Benefits

Partnering implies a shared purpose, a desire to collaborate for the common good, and perhaps a better, faster way of getting things done. In the context of managing clinical trials, partnering has been fundamental for decades. Sponsors hire clinical research organizations (CROs) to manage clinical trial sites where investigators, in turn, depend on a variety of healthcare providers, including nurses, technicians, and office managers, to keep trials on track.

However, a new era of DCTs is dawning and is revolutionizing the conduct of trials by bringing the trial protocols directly to patients, who can engage with investigators locally, where they live and work—even in their homes. DCT technology is a tremendous boost to trial patient recruitment, retention, and population representation while capturing rich, real-world data (RWD) and reducing costs. Significantly, a new study from Tufts Center for the Study of Drug Development shows that, on average, DCTs can achieve net financial benefits ranging from five to 13 times for Phase II and Phase III trials, due to reduced trial timelines and other factors.

Even with these benefits, the industry is wading through how to implement the DCT model most effectively and at scale. To navigate these new waters, leading organizations are coming together to create an ecosystem of best-of-breed, trial-enablement providers. This network of like-minded organizations includes CROs, traditional and nontraditional investigator sites—new retail pharmacy sites among them—and leading data and technology service providers for biostatistics, electronic data capture (EDC) solutions, data repositories (such as electronic health records [EHRs]), workflow management, systems integration support, and more. These partners share a single mission to get more effective therapies to patients faster.

“There are a lot of moving parts in a DCT, but you cannot have more than 300 points in a value chain because that creates transactional inefficiencies and impossible-to-manage complexity,” explained Avi Kulkarni, vice president and life sciences research and development lead at Cognizant, a systems integrator. “On the other hand, one company cannot possibly innovate at every part of the value chain, so a limited ecosystem of best-in-class partners provides sponsors with the right balance of skill sets and manageability.”

A DCT partner network has the same hallmarks as today's e-commerce systems for consumer goods—removing transaction friction between consumers, retailers, banks, and delivery systems to enable quick response and satisfied customers. Of course, running a clinical trial is a vastly different process than fulfilling a grocery purchase, but the common element is foundational technology that enables data to move seamlessly between systems.

Five Components to a Successful DCT Ecosystem

1. Service partners—including CROs and systems integrators that provide outsourced expertise for trial deployment, project management, and support. For example, Advanced Clinical, Parexel, PPD (part of Thermo Fisher Scientific), Syneos Health, and other CROs can build and deploy clinical trials with certified expertise. Top consultants (e.g., Accenture) and system integrators (e.g., Cognizant) bring certified expertise in decentralized and hybrid trial deployment, study management, data analysis, insight generation, site relationships, and process optimization.

2. Data partners—enriching clinical trial data with real-world data is pivotal to accelerate effective therapies to patients faster to create a holistic profile of the patient and provide solutions for long-term follow-up after trial completion. Data providers are critical in helping connect real-world health records, claims, diagnostic, and other data sources with trial data. Connecting real-world data reduces the burden on patients and helps trial teams augment evidence before, during and after studies. This empowers sponsors to create compassionate engagement strategies to remain connected with patients post trials.

3. Technology partners—when leveraging a variety of software, data, and wearable/connected devices, ensuring interoperability across systems is critical to providing a seamless data flow and experience for sponsors, sites, and patients.

4. Direct-to-Patient partners—these organizations enable a patient concierge experience with home-health nursing and at-home testing and diagnostics. At-home sample collection and diagnostic partnerships improve patient enrollment, for example, and help the discovery of new biomarkers while reducing patient burden. Vault Health, which sold more than 10 million COVID-19 tests for at-home use, is one example.

5. Site partners—these partners can include traditional sites and academic institutions as well as nontraditional retail pharmacy locations such as CVS Health to expand clinical trial access and engagement in their own or nearby communities for patients who cannot travel to distant clinics.

Services Partners: Providing Strategic Expertise

CROs play a central role in most clinical trials, and when they can draw on the talents of a partner ecosystem, a better outcome can result. Noolie Gregory, vice president of DCT operations at Syneos Health, noted that study setup can involve an elaborate negotiation with the study sponsors themselves. To simplify this, it helps to have a coordinated approach that addresses the sponsor's specific needs.

“When we come together as a connected ecosystem of value-add partners, we can offer sponsors reliable, validated choices [concerning] the right technology [and] tools—and whether we need to focus around [electronic clinical outcome assessment] or integrated wearable devices or [on visualizing] data in a new way or mapping specific [key performance indicators]...that is where you have the benefit of those partnerships,” said Gregory. “We can start solving on a portfolio level rather than project by project.”

At the same time, CROs are working with various patient-facing, operational organizations to ensure that trials can proceed effectively and therefore can capture broader insights to fuel continuous improvements in DCTs. “For example, we can track how telemedicine is working across all suppliers and all trials to identify any common problems and address those for all,” Gregory added.

Some of Syneos' clients want an enterprise-wide DCT approach, which calls for additional expertise. “We are working strategically with companies who want a holistic DCT strategy across the organization to find the right approach sensitive to their pipeline, their therapeutic focus, and their organization,” said Gregory. “It's a transition period—everyone is at a different point on the change management curve. There are early adopters and laggards who are less certain, and that is human nature. A trusted partner ecosystem gives sponsors greater confidence wherever they are on the curve.”

Data Partners: Creating Seamless Data Integration

The fragmentation of health data is one of the greatest challenges facing healthcare today. Patients have a multitude of interactions with healthcare systems throughout their lives, and that information is retained in siloed databases across disparate institutions. With clinical trials being one of the most critical sources of evidence on drug effectiveness and safety, it is imperative to bridge the gap between clinical trial data and RWD to expand and extend trial value. DCTs naturally foster more RWD from various connected devices and wearable sources that, when combined with other clinical trial data, provide higher fidelity of efficacy and safety.

“Trials represent just a sliver of the data that describes patient health,” said Vera Mucaj, chief scientific officer of Datavant. “Linking [EHRs] and mortality data can support long-term safety and effectiveness measurement. Connecting insurance claims can add evidence of cost-effectiveness. And, connecting [RWD] to DCTs augments trial evidence at a fraction of the cost of collecting data through a traditional clinical study.”

When specialized data providers are part of a connected ecosystem organized to facilitate easy data access and sharing, it is possible to seamlessly incorporate patient health data sources like EHRs and RWD into the trial. In this way, sponsors can optimize protocol and study design by adding richer clinical details about patients’ health. Better information available in real time also helps ensure participant retention the duration of a trial because it empowers study teams with the information to expedite any necessary patient support.

Technology Partners: Ensuring Interoperability Across Systems

DCTs often require multiple systems across the value chain, but the greatest value comes when these systems are connected in a vetted ecosystem of best-in-class providers who already have an in-depth understanding of the many nuances in the life sciences industry. For patients, system interoperability simplifies the remote clinical trial experience. For investigator sites, it simplifies their workflow and provides a consolidated, single source of truth with real-time access and single data entry (avoiding redundant work for staff). Finally, sponsors benefit with improved compliance and increased data quality with a streamlined workflow plus complete visibility into all activities across studies.

For example, Oracle's Clinical One system brings together various data sources—including sites, eConsent forms, wearable sensors, patient apps, EHRs, and labs. This enables all study partners to make better decisions through access to hundreds of data types from extensive external sources across interactive response technology, EDC, clinical trial management systems, custom systems, and more.

“Being part of a partner ecosystem streamlines decentralized trials and puts the patient at the center of the trial while providing robust data analysis for sites that can unlock better insights and ultimately better outcomes for sponsors,” said Henry McNamara, senior vice president and general manager of the Health Sciences business unit at Oracle.

Direct-to-Patient Partners: Providing the Human Face of DCTs

The organizations that engage in direct patient interaction are on the front line of trials and crucial to the success of a DCT. They are the human face of what can seem a cold, sterile process, so it's important to align with partners with shared goals for patient care.

“We do much of the hard work of the clinical trial,” said Alexander Pastuszak, MD, PhD, president for clinical care and chief clinical officer at Vault Health. “We interact with the patient via telehealth or at home. We support DCTs with specialized services that fill the gaps of commonly used digital technologies, doing this at scale through clinical study staff and the technology that supports them. For instance, we can provide investigators and virtual sites for studies and send clinical practitioners to do in-home patient assessments and collect diagnostic samples, and then ensure those samples get to the right labs, quickly and efficiently. As a part of an ecosystem, we capture these interactions and the data that go with them in a single system that informs the rest of the trial.”

Pastuszak continued, “A DCT partner network is hugely valuable to sponsors. It streamlines the number of different vendors down to the very best few, simplifying trial management complexity, but still providing sponsors with choice. In addition, it allows sponsors to fill in the gaps by engaging a network of best-in-class capabilities to optimize the trial process. At this point, a single entity that tries to provide all DCT services will only have a mediocre result and that benefits no one.”

Site Partners: Improving Patient Access and Experience

DCTs expand site access by connecting patients with remote sites, offering easier ways to collect patient data, and bringing the onsite experience home using telemedicine. However, it's critical to empower sites with customized training modules, best practices, and individual certifications to expand decentralized trial knowledge. This is one advantage of leveraging site partners already trained and certified on DCTs. It removes some of the friction that comes with change management.

The Value to All

A collaborative ecosystem, rather than any one company alone, allows sponsors to scale their strategies to put patients at the center of care with remote trial access, superior user experiences, and a range of services, connected devices, and data sources. An ecosystem of best-in-class partners provides differentiated value through strategic alignment across therapeutic areas; preconfigured solutions for faster go-to-market delivery; technical enablement for user adoption; and trial design innovation.

Of course, partner networks are not a panacea—they can be set up well or poorly, and coordination can be smooth or rough. However, when there is a reliable technology platform that interfaces smoothly with both the tech and human elements of trial management, there is great potential to leverage all the advantages of DCTs. In other words, done right, a network improves the trial experience for all.

Patient experience and safety are improved by ensuring appropriate trial continuity and proactive care. Sites benefit by being able to differentiate to provide long-term, compassionate patient engagement. DCT technology that can track and follow patients for five to 10 years or more improves sustainability of care. Further, for sponsors, RWD can be incorporated to improve protocol and study design, thereby improving enrollment and outcomes. A DCT partner network also adds layers of patient and trial insight for ongoing improvement as the industry continues marching down the road of DCT transformation.



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TRIALS & TECHNOLOGY

Unique Considerations in Designing Decentralized Trials for Digital Therapeutics

Pam Diamond, MD



Digital therapeutics (DTx), the use of software-based interventions to prevent and treat disease, is one of the biggest areas of growth in life sciences. CB Insights reported that 2021 funding in the digital health industry [grew 79% over 2020](#),^{1} and the global DTx market is projected to hit [\\$13.1 billion by 2026](#), up from \$3.4 billion in 2021.^{2} Many say digital therapeutics will re-write the future of healthcare.^{3}

The DTx industry isn't just aspirational. Studies show improved outcomes from DTx, either alone or in conjunction with conventional therapeutics, in a broad range of indications, including cancer, ADHD, asthma, schizophrenia, and insomnia. Some examples of products include video games to treat mental and behavioral health issues; a platform that incorporates neurological music therapy, sensors, and artificial intelligence to help patients who have suffered a stroke or other neurological disorder to rebuild motor skills; and a smartphone app that can conduct electrocardiograms anytime, anywhere.

Background

While exciting, this is still uncharted territory. Regulatory lines are often blurry between prescription DTx, non-prescription DTx, and combination digital therapeutics/traditional medication. It's worth noting, however, that the U.S. Food and Drug Administration (FDA) has demonstrated its commitment to supporting digital health technologies through the publication of multiple guidance documents and the launch of the Digital Health Center of Excellence, which

aims to connect and build partnerships to accelerate digital health advancements, in September 2020. In April 2021, too, the FDA loosened [regulations](#) surrounding approval of digital mental health tools to hasten their time to market.{4}

Even so, not all DTx manufacturers choose to seek FDA approval, but they all need to prove efficacy through clinical studies for payers to consider coverage and consumers to consider purchase. Regulatory approval is not always the end goal—or at least, not initially.

AstraZeneca, for instance, has designed a rigorous and low-patient-burden digital therapeutic to monitor metastatic breast cancer patients. The prescription DTx, which is currently being tested in clinical trials in 23 countries, was developed using insight from a review of medical literature, pulmonary and breast cancer experts, technology review, and real-world evidence gathered through conducting a deep cohort analysis of approximately 500 patients in U.S. health systems.{5} The therapeutic’s aim is to monitor patients’ symptoms and vital signs and, based on algorithms and expert rules, alert a physician as to how well the patient is doing on the treatment to maximize both safety and outcomes.

“Regulation will differentiate between a fitness app a consumer can simply download, with no regulation required, versus something that is scientifically proven to have a direct impact on someone’s health condition or outcome, which a doctor may prescribe,” said Cristina Duran, chief digital health officer for AstraZeneca, in a statement. “In a few years, I think we will see that shift to it being commonplace for your doctor to prescribe a digital therapeutic, a medication, or both.”

Indeed, it’s a complicated and quickly evolving arena in healthcare.

On top of the current regulatory limbo, DTx manufacturers face many of the same clinical trial challenges as traditional drug makers, including those tied to patient recruitment and retention, quality of data, and costs. They also must carefully consider the unique technical security concerns of an all-digital therapeutic and face strategic decisions around either provisioning smart devices or leveraging a “bring your own device” (BYOD) policy. At the same time, clinical trial models are rapidly evolving, adding further complexity for companies working to develop innovative digital therapeutics in a post-pandemic environment. Decentralized clinical

trials (DCTs) are becoming a preferred model for research in biopharma and offer even greater benefits to companies conducting studies on digital therapeutics.

Wave Neuroscience, a medical device manufacturing company that specializes in designing software and physics-based personalized brain-based interventions, is moving toward more decentralized clinical trial designs. “DCTs can improve patient recruitment and retention by reducing burden and eliminating geographic barriers,” explained Dr. Erik Won, president and chief medical officer of Wave. “This also results in a more representative sampling of the population, such as patients from rural areas who often don’t have access to major institutions.”

Dr. Won continued, “DCTs can also increase the quality of data by minimizing the Hawthorne Effect—where individuals modify an aspect of their behavior in response to their awareness of being observed, also known as ‘white coat syndrome’—because patients are in their home environment.” Finally, DCTs can be more cost-effective, he added.

When Stars Align: DCTs and DTx

Fundamentally, a DTx is software rather than a pill or injectable, so there is no distribution or administration of medicines. There are no physical logistics—no shipping, storing, chain of control, cold storage, or biohazards—plus endpoints can be captured within the DTx application itself, making DCTs ideally suited for DTx studies whether the goal is regulatory approval or consumer and payer confidence.

In all cases, though, the unique advantage is that the DTx being studied in a trial is also the data collection device, so manufacturers often don’t need extra technologies like an electronic patient-reported outcome (ePRO) system to capture data in a clinical trial. It’s all in one, and this can result in big cost savings.

For example, Texas A&M and Wave Neurosciences are conducting a hybrid clinical trial on the safety and efficacy of magnetic EEG-guided resonance therapy to treat post-traumatic stress disorder (PTSD). This therapy uses transcranial magnetic stimulation, which has been cleared by the FDA for treatment-resistant major depressive disorder, obsessive compulsive disorder, and nicotine cessation. With this algorithm-driven therapeutic, a personalized treatment is delivered

via conventional (in-person) appointments. Screening and follow-up visits, in which participant-reported data are collected, take place virtually to the extent possible.

“America is experiencing a crisis in mental health,” said Dr. Won. “Software- and physics-based personalized therapeutics are a modern, non-pharmaceutical, non-invasive option to help in this area. We are testing our therapeutic with an eye to pursuing an FDA marketing approval for the PTSD indication. We are exploring the decentralized trial model to introduce greater flexibility and speed into our research efforts.”

Best Practices for Designing DTx Trials

With the quickly growing and evolving DTx market, and the complexities associated with clinical research, here are five considerations for decentralized trial design:

1. Know your regulatory roadmap before embarking on a trial.

Because the regulatory pathway for digital therapeutics is not as clear-cut as it is for traditional investigational drugs, it is critical to outline your regulatory roadmap before recruiting the first patient. Feasibility studies can be a good place to start, especially to help map out an expansion plan down the line. Some important considerations also include how future versions of your DTx product will be tested, benchmarked, and evolve over time.

“It is always best to seek meetings with the FDA’s device division [the [Center for Devices and Radiological Health](#)] early, and often,” said Dr. Daniel Karlin, chief medical officer at MindMed, a clinical stage biopharmaceutical company developing novel products to treat brain health disorders. Dr. Karlin is also the lead medical advisor to the makers of the first and only FDA-cleared, prescription DTx that improves sleep in adults 22 and older with nightmare disorder or nightmares related to PTSD.

Dr. Karlin continued, “It is easier for DTx providers to secure meetings with the FDA because digital therapeutics are typically less biologically complex and therefore pose less risk. Request a meeting at the start of your development efforts to agree on the claims you plan to make based on the indication for use, and to establish what related evidence will satisfy the FDA. This is

fundamental. Also, seek institutional review board [IRB] clearance on anything that could conceivably be research-related before you bring an experimental device to humans for studies.”

Of course, regulatory approval—while often considered the ultimate validation for the safety and efficacy of a drug or device—isn’t the only reason for conducting clinical research, especially with DTx. Health economic outcomes and human factor research are often equally important for product adoption. Even in the digital realm, real-world function and outcomes are important to create products that lead to meaningful outcomes for patients. “All manufacturers want payers and patients to be confident in our product’s efficacy, safety, and economics,” added Dr. Won.

For instance, some DTx products that have minimal risk may not require regulatory approval but are just as valuable as those that do. Decide if regulatory approval is on your short-term or long-term roadmap and design the trial accordingly. If it is not, then there is greater flexibility in study design.

2. Map out an immediate and long-term commercial strategy.

Given how quickly the DTx marketplace is evolving, the best that can be done may be to sketch out a preliminary commercialization strategy that has plenty of leeway to deviate from that path, if necessary. For instance, if your therapeutic will not be intended for regulatory approval, you may need to focus on a consumer strategy that focuses on everyday wellness. If you know this up front, you can design your clinical trial around endpoints that mirror your target consumer’s biggest pain points. However, if your end-goal is to develop a DTx that will be used in combination with an FDA-approved drug, then you will need to design your trial based on endpoints relevant to that drug maker’s target patient population.

3. Carefully consider and incorporate protections against technical security breaches.

Data security and privacy are crucial for all clinical trials, but especially when studying DTx that are 100% tech-driven and, therefore, potentially vulnerable to more issues. One of the most important decisions that needs to be made up front is whether the protocol will strictly enforce a BYOD strategy (which could prevent some patients from participating) or require the sponsor to

provision devices to all participants (which could be cost-prohibitive)—or some combination thereof. Each option comes with different security considerations, so decide this up front.

Regardless of device strategy, all data collected on the smartphone will need to be encrypted and then sent to a secure central platform in the cloud that follows all regulatory compliance parameters. Additionally, invest in a platform provider or tech-enabled CRO that maintains a strict security perimeter, including a “zero-trust” architecture with individual logins and audit trails for everyone who has access to the data every time they log in or out—this, on top of the digital therapeutic app’s security standards.

4. Develop digital endpoints that are fully validated and meaningful to patients.

Traditional medicine trials measure against accepted endpoints that are validated in accordance with standards set forth by the IRB and regulatory organizations. However, DTx studies are typically measuring novel digital endpoints that are different for each DTx app and do not have a history of vetted benchmarks against which to be validated. Even so, reviewers will need to ensure that the novel endpoints aren’t bogus, and this can require some extra steps and creativity.

In many cases, endpoint validation in DTx studies requires a comparison to something similar that has been already validated or the use of previously vetted ratings scales. For example, when conducting a depression study, the DTx sponsor may first administer the Columbia-Suicide Severity Rating Scale—a suicidal ideation and behavior rating scale created by researchers at Columbia University, University of Pennsylvania, University of Pittsburgh, and New York University—to potential participants at screening. The patient’s score can be the baseline for the study, so if the DTx is efficacious, that score should drop and serve as a validated digital endpoint for symptoms of depression.

Similarly, DTx studies may leverage ePROs to administer quality-of-life questionnaires compared against prior research already accepted and validated by the IRB and FDA. Another way to validate endpoints in a decentralized DTx trial is to incorporate an initial site visit with a clinician who can compare the measurement of, say, a wearable device against an equivalent onsite, hospital-grade machine. Doing so can prove the wearable is as valid a measuring tool as another.

Finally, as important as endpoint validation is patient validation—in other words, identify the measurements or endpoints that are meaningful to patients. For example, with Fern Health’s digital musculoskeletal platform, the company shifted the focus of pain management from pain relief to functional restoration. Early on, the company found that functional pain endpoints are more important to patients in the long term than pain relief alone and made that critical adjustment.

5. Assess the use of DTx placebos or sham apps early and often.

In a DTx clinical trial, dummy or “sham” apps are often used as a control in comparison to the actual treatment or intervention app—like a placebo pill used in a randomized control trial. There are unique [considerations](#) in using sham apps, however, including the potential for an unintentional placebo effect.

Here is the challenge: It is very difficult to make a sham app similar enough to the real one, which means patients often suspect that they were not assigned to the treatment arm. In addition, patients who do interact with the sham app can experience a placebo effect that negatively skews study results. For instance, patients in the treatment arm of a study would typically show significant symptom improvement compared to the non-treatment arm, but when using a sham app, that disparity is not as dramatic.

The FDA has not yet ruled on whether placebos or “sham” apps must be used in DTx trials, but the agency often prefers a sham control. DTx companies that opt not to use a sham control will need to work very hard to find creative ways to design an FDA-acceptable trial that won’t be criticized—even then, there is no guarantee that the FDA will accept the results.

“It is highly unusual to view sham controls as unnecessary in clinical trials,” said Dr. Karlin. “Not only do regulatory bodies prefer sham-controlled evidence in digital therapeutics studies, but also clinicians. Reluctance to use sham apps will cause companies to struggle to get both FDA clearance and physician buy-in, which is critical for commercial success with patients.”

Dr. Karlin’s team for the PTSD DTx leveraged a sham control on a wearable device that, rather than buzz when detecting a nightmare, simply recorded it. “When we assessed the reliability of

our blind through a survey of our trial participants, we found that most did not know whether they were using the real therapeutic or the sham,” he noted. “This helped validate the research because it meant that we could reliably compare the active intervention with the placebo for more meaningful results. Randomization and sham control are not magic bullets, but they’re the best options we have right now.”

As the Digital World Turns...

There’s still a lot to be learned in the DTx market, but they are here to stay with growing reliance, trust, and adoption of digital health products. COVID-19 pushed researchers to lean into the decentralized model for research, and the pandemic has simultaneously fueled a growing need for DTx products—an ideal marriage of process and product. Remaining flexible and open-minded will be critical to succeed in this evolving and exciting area—as the digital world turns.

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ON THE JOB

Revolution of the Clinical Data Analysts: How Innovative Trial Methodologies are Opening Up Career Opportunities

Marthe Masschelein



Clinical research is in the grips of a revolution that has caused a wave of new career opportunities.

The digitalization of trials and centralized statistical monitoring, for example, has generated the need for a new breed of data analysts—people with a broad range of skills and with a promise of significant job satisfaction.

This column focuses on the evolving role of the clinical data analyst, how such analysts contributed to the development of the Pfizer-BioNTech COVID-19 vaccine (Comirnaty®), and the future of clinical data analytics.

A Unique Skill Set

The industry has seen a shift in how clinical trials are designed and conducted in recent years.

Advances in computing power and data analytics have contributed to the birth of centralized statistical monitoring, which replaces traditional, retrospective source data verification with the near real-time analysis of data as they accumulate.

Assuming that data generated at each site should be roughly similar, analysts compare the collected information to identify site-level, country-level, and patient-level “outliers” for further investigation.

The review of anomalies in the data protects data quality by alerting sponsors to potential issues and enabling them to take corrective action before the problem can impact data integrity. In turn, this optimizes development pathways and shortens time to market access.

This enhanced way of conducting trials has given rise to a new breed of clinical data analysts.

Parts of a (Whole) Role

The goal of clinical data analysts is to identify anomalies in the data that could indicate a potential risk to the customer. So it’s all about data quality and integrity, and there are two main parts to the role.

The first is the system setup, which includes data consolidation. This involves harmonizing all the data from the customer’s various data sources, such as the electronic data capture and laboratory data, and feeding it into a risk-based quality management platform.

Second, a statistical engine is applied to all that data and the relevant results collected for review. Analysts will look for atypical data patterns, describe them in a “risk signal,” and present these signals to the customer’s study team. The analysts then support the team to decide whether the signals reveal a (potential) risk for data quality and integrity and whether they require continued monitoring or immediate follow-up (e.g., further investigation or corrective measures).

Probably the nicest part about the analyst job is that it takes a process from beginning to end—from uploading the data to presenting the results—rather than just covering a small part of the action.

This well-rounded process, however, is not for everyone, as the two parts of the job require different skill sets.

For the data harmonization and system setup, analysts need to do some SAS programming, although it isn't very advanced, and data management and data manipulation. They need some technical aptitude and critical thinking skills—an analytical mind to review the data. They need good writing skills to describe the signals and good communication skills to present them.

The role may change as the organization scales and leaves its start-up roots behind. There may be opportunities for people to specialize in specific parts of the pathway, whether data harmonization, set-up, data review, or presenting the signals. This would allow people to play to their strengths while also honing their skills in other areas.

Rewarding Work

Analysts like the ones on the author's team work in pairs for quality assurance and very closely with their customers, almost like an extension of the in-house study team. This can enrich professional relationships for both the analytics service provider and the sponsor.

Multiple clinical data analysts were, for example, part of a team from the author's company that worked on the statistical analysis of data from Pfizer-BioNTech's COVID-19 vaccine trials, helping to accelerate the development of this time-critical mRNA drug product. The safety and efficacy study was highly complex and recruited at a rate of 5,000 people a week. It combined Phases I, II, and III and included more than 43,000 people from 150 global sites, generating a massive volume of data.

The team supported Pfizer's in-house analyst group by performing daily data analysis to ensure risk signals were identified, investigated, and mitigated in near-real-time and developed a suite of data visualizations to communicate potential risk areas. This allowed Pfizer to increase efficiencies so that it submitted drug applications in record time.

Analysts also work closely with other departments, such as the product, research, and commercial teams, making the role extremely varied. According to their assigned subject matter expert specialties, analysts further act as mentors to junior members of the team and customers. Having so much interaction with people in different clinical research functions and roles enables analysts to learn a great deal and build their expertise in new and vital areas.

Future of Clinical Data Analytics

Clinical research is evolving rapidly, making it something of a challenge to keep up but also presenting aspiring clinical data analysts with tremendous opportunities. Roles at companies specializing in centralized statistical monitoring are unique in that they embody a best-in-class approach to conducting clinical trials. These companies are always looking for people who are interested in and have a passion for the profession and for finding ways to make clinical trials better. Who doesn't want to do that?



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PRESCRIPTIONS FOR BUSINESS

Four Ways Digital Clinical Trials Empower Research Sites

Bree Burks, RN, MSN



Clinical research sites are under more pressure than ever to move faster and be more efficient. Without the right digital tools, it is challenging to keep pace while maintaining quality. Labor-intensive processes, large volumes of paper documents, and ever-increasing operational costs can create a cumbersome approach to clinical research management.

Despite these operational inefficiencies, many sites are reluctant to explore new technologies since their biggest challenge is having too many systems with different processes and logins.^{ 1 } Sites use a mix of their own technology and sponsor applications, so staff often have to duplicate work or maintain complex integrations across two environments.

A digital clinical trial brings together study stakeholders, linking sponsors, sites, and patients for seamless information exchange. To advance toward this reality, site-centric technology is unified with sponsor systems for clinical operations, data management, and patient-facing applications. For example, an eRegulatory system (or electronic investigator site file [ISF]) that connects to the sponsor's electronic trial master file (eTMF) can be used for all studies. This would help sites streamline site operations and decision-making, enable easy collaboration with sponsors, and deliver a better patient experience.

Moving beyond function-specific solutions can enable a more connected, digital clinical trial. Here are four ways this can streamline processes to boost efficiencies for sites.

1) Improve the Site and Sponsor Relationship

The transactional nature of clinical trials is slowing down processes. For example, 78% of sponsors and contract research organizations (CROs) still use e-mail to exchange information with sites during a trial.^{2} The widespread use of e-mail makes it hard to keep track of activity and leads to multiple requests for information, missed messages, and duplication of effort. Add to that paper shipments, file shares, and portals, and the coordination of information exchange gets more complex.

Lorena Gomez, global head of study start-up, patient-reported outcome management, and digital implementation at AbbVie, understands the challenges sites face working across studies with multiple systems. “Site personnel likely receive several requests from a sponsor asking for the same documents. That is not site-centric and leads to uploading multiple copies of the same documents into the electronic trial master file (eTMF),” she says. “A unified digital clinical trial platform can eliminate these manual, redundant requests, enabling more focused, meaningful conversations between sites and sponsors at the beginning of the study.”

A digital clinical trial that brings together site- and sponsor-owned systems can significantly reduce e-mail traffic since most requests can be digitally executed or automated. This improves communication across stakeholders and reduces frustrations with duplicate information requests or last-minute scrambles to search e-mails and find documents. When sites and sponsors work better together, communication is elevated beyond transactional requests, leading to a stronger relationship. Some sites are already experiencing time-saving benefits from a single system.

“Using a unified system helped us reduce e-mail communication significantly,” said Jim Sanders, president of ClinOhio Research Services, LLC. “During study start-up, we went from sending about 140 to 150 e-mails to the sponsor to only sending 30 to 35, improving our overall communication during the study.”

2) Optimize Site Operations

Digital clinical trials can simplify information sharing to improve site operations, free valuable time for site staff, and speed study start-up. This is critical to accelerating trials because 61% of trial lifecycle times are spent on early trial processes.{3}

For example, when a site receives a start-up package, documents are accepted and auto-filed within their eRegulatory system. Study teams can then route documents for training, collect signatures, and share completed documents with the sponsor seamlessly. With no additional work or custom integration, CVs, medical licenses, and certifications sync automatically to the sponsor's eTMF.

Completing these tasks within a connected, site-centric system powers more intelligent reports that automate reconciliation and provide visibility into key metrics, like expiring documents, open tasks, and outstanding signatures. “Our eRegulatory app is much easier to use, allowing us to move faster, and the sponsors like it because they know they’ll have real-time information at their fingertips,” adds Sanders.

3) Standardize the Way Sites Work with Sponsors

The typical research site works with 12 different systems to collect clinical research data,{4} but this isn't a sustainable way to work. Sites need ways to reduce multiple technology trainings, logins, and passwords to streamline processes during trials.

A site-centric system that connects to sponsors centralizes information for standardization across studies. Using a standard eRegulatory system to complete tasks and share documents reduces training and administrative burden. It also ensures the ISF is consistent across sites and studies.

Standardizing processes can reduce the time spent reviewing the ISF and reconciling documents, allowing study monitors to focus on value-add activities such as site processes and safety reviews.

4) Provide a Better Patient Experience

While COVID-19 accelerated the move to decentralized trials, it underscored the importance of the holistic patient experience. Digital clinical trials can significantly enhance the patient experience by improving the consent process and delivering greater convenience.

“The implementation of digital solutions will allow the industry to minimize the amount of time and commitment that patients have to spend in an office,” says Gomez. “That’s better for the patient, site, and sponsor.”

An end-to-end digital platform with connected applications allows for seamless, automated workflows. The sponsor can author a consent form, send it to the site, get it approved by the institutional review board, and signed by the patient in one activity flow. The benefits include a more informed and engaged patient throughout the trial, enhanced access to more diverse patient populations, better tracking of patient consent forms for sites, and greater visibility into the consent status for sponsors.

Enabling a More Connected, Digital Trial

The rapid shift to decentralized trials during COVID-19 highlighted the need for better management of documents and data through direct digital connections that link sponsors, sites, and patients. The industry is making progress in terms of moving toward digital clinical trials that enable seamless collaboration across stakeholders. This is good news for research site leaders since they will be able to reduce administrative burden and reap the efficiency and time-savings of unified, site-centric systems.

With fewer manual or redundant tasks and more automation, sites can improve operations, simplify their work with sponsors, and better care for patients. At the same time, sponsors can access information in real-time and have confidence documents are always current. A digital and connected study advances the industry, shifting processes from being paper-based and manual to digital and automated. As research sites capitalize on the efficiencies of unified systems, they play a critical role in accelerating clinical development for patients in need.

To learn more about this topic, visit the ACRP 2022 [Online Conference Library](#) and look for the sessions on “Working Better Together: How Technology Brings Sites and Sponsors Together” and “Embracing a New Technology Era in Clinical Trials: How Digital, Connected Trials Transform Site Operations.”

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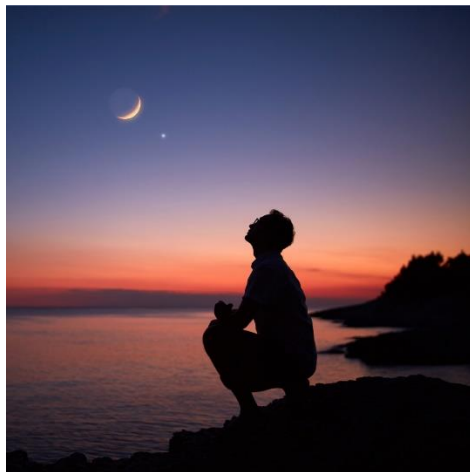


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RECRUITMENT & RETENTION

Opinion: We Have Been Gifted a New Outlook on Increasing Patient Diversity, Compliance, and Retention in Clinical Trials

Wessam Sonbol, CSM, CSPO, ICP-ACC



The COVID-19 pandemic has changed the entire world over the last two years. Life, as we knew it, stopped. Terms like “social distancing” and “masking up” will now be a part of our lexicon forever. In our industry, 70% of clinical trials were put on hold with everyone in clinical research, and the healthcare profession at large, shifting efforts to create and test vaccines and anti-viral medications and even to testing for the virus itself. The pandemic has undoubtedly had a profoundly negative impacted on all of us, professionally and personally. However, professionally speaking, these real-world challenges may have also given the clinical research profession the gift of perspective that will positively affect the outlook on our industry’s collective future.

The clinical research industry was challenged to find solutions regarding how to safely continue conducting clinical studies. The quickest solution that was within reach was incorporating ideas that were already a part of our community’s discussions—*remote patient monitoring* and *decentralized clinical trials* (DCTs). These topics had been discussed, and even implemented over the past few years, but not widely adopted yet. The circumstances of the pandemic made “discussions” of what could “theoretically happen” become re-framed into questions of “how do we make this happen?” and “how can we pivot our model to continue clinical trials in the current climate?”

For the past few years, industry leaders have forged a future-focused path by embracing technologies such as wearables and biosensors. Now, on a larger scale than ever before, the industry is adopting these types of devices in order to monitor trial participants and patients safely and remotely from home. Clinical research and trials have resumed as we continue to make progress and more widely accept and adopt a variety of technology platforms and solutions—tailoring them to meet the needs of all types of clinical studies.

As a silver lining in these unprecedented and challenging times, our industry has “stepped up” to also be thoughtful about how more widely incorporating these technologies may assist our profession in meeting the calls to increase patient diversity in clinical trials. A benefit to using wrist wearables and biosensors will be that the path forward to supporting DCTs will be within our reach.

Imagine how many potential patients your study may have if trial patients don’t have to worry about access to transportation; or if they don’t have to live in a certain geographical location to participate. How many doors would that open to underrepresented populations? Whether they are considered underrepresented by race, ethnicity, gender, or age group, or because they physically live in more rural locations, DCTs may level the playing field by allowing potential study participants to join in who may have never otherwise been granted access to studies. What may have seemed out of reach might now be a real, viable option for them. We know that increased patient diversity leads to better quality data, which in turn leads to better trial results and a more successful trial overall.

Adopting Technology Solutions and Setting New Standards for Clinical Research

The clinical research industry is critically important in times like these and, therefore, we must continue to forge a path forward. While we might want things to “return to normal,” we must also accept we are not in a “post-COVID” world just yet. We must stay focused and use every tool at our disposal to take advantage of hybrid and DCT models, in order to provide a way to keep patients safely at home while simultaneously looking toward the future of advancing clinical trials by utilizing a mix of technology platforms and solutions to remotely recruit, consent, and randomize patients, and to collect digital endpoint data directly from them.

While integrating wearable technology is an important part of setting new standards and best practices, it does not work independently of other facets that must also be considered. Our new outlook must identify, consider, and use every possible solution in our arsenal—including, for example, leveraging in-home nurses to collect blood samples and conduct in-home labs. We can customize solutions for our clients by taking advantage of infrastructure that already exists by re-tooling it to fit the needs of a “COVID climate” and even the realities of a “post-COVID” world. While many have taken these steps over the last few years, we should continue to modify and improve our solutions. This allows for us to partner with our clients in order to thoughtfully design more DCTs, an effort which reduces the need for in-person clinical visits; cuts costs; potentially increases patient participant diversity; and leads to improved data quality—all of which will continue to help bring solutions identified by clinical trials to the marketplace more efficiently.

In recent years, not only have the physical devices used in telehealth significantly changed, but the software solutions that power them have advanced more quickly than we ever expected. Companies within the clinical research enterprise have advanced their web-based and mobile applications to keep up with technology’s forward progress. App-based solutions can be fully integrated and connect across almost any connected, wearable device. Additionally, some technology platforms feature and leverage artificial intelligence (AI) tools that may otherwise already exist inside patients’ homes, like Amazon Alexa or Google Assistant. AI tools that exist as a part of clinical research-based apps may also now be leveraged and automated to communicate with other such apps—improving data outcomes.

These features may become beneficial as they will most likely have a positive impact with regard to effectively monitoring patients remotely. For example, AI tools can be implemented in multiple languages and used to learn and then understand the best way to engage with a patient. Another example is that AI tools developed for customizable solutions can utilize mobile apps, SMS, and automated phone calls in order to nudge and notify a patient of upcoming visits, eDiary entries due, and medication adherence questions—all ways to keep the patient compliant and engaged in every step of the study.

Patient Compliance and Retention are Paramount

Patient compliance and retention in clinical trials are key components of conducting a successful study. The overall patient experience is paramount. If the patient participants in a study find the paperwork cumbersome or stressful, many will not comply in a timely manner or provide a full log at all. We all know how critical detailed and completed diaries are for investigators, and other members of the clinical research team, to be able to efficiently and accurately compile the data and conduct their necessary analysis. When patients are noncompliant (i.e., not completing diaries or not regularly using their wearables) or drop out of a study altogether, it creates a multitude of issues, including steep financial losses, which can threaten a study's success.

How Can Technology Help?

Technology companies within the clinical research enterprise have developed platforms that can be helpful in identifying and solving some of these obstacles. Any cloud application should have the ability to integrate with virtually any type of connected devices, making wearable device and biosensor data actionable.

Wearables, in general, can revolutionize our field. As we've stated before, wrist wearable technology can be used as a tool to help provide remote patient monitoring and can deepen the understanding of how patients are doing when they are away from the clinic. While these devices have been used in our field in the past few years, it is our new outlook that has us exploring how we can maximize the benefits of technology. It is a laudable goal to further enhance the patient experience by offering a solution that allows their wearable to integrate with other tools that may possibly already be available in-home.

The more integrated a study's requirements are to a patient's everyday life, the more compliant they will be. One goal should be to customize a solution to meet the needs of each specific clinical trial and, more importantly, to make it easy enough for patient participants to comply in a timely manner. For example, if a patient is not wearing his or her device, no data are shared with investigators. Again, many of these applications have an AI algorithm, which allows the system to learn to engage the patient in different ways to identify the best options for compliance, based on the study participant's behavior. Some of these apps also have the ability to alert investigators

in real time, so that they can follow up with participants to encourage them to complete the tasks required. Another example is the utilization of SMS text messages for updates of trial progress and upcoming visit reminders, lab reminders, and other notifications, which keeps the study and all the information that comes with a patient's participation at the forefront of their mind.

The end-goal should *always* be the patient, so the technology needs to allow real-world data and real-world evidence from the device to be downloaded and used as a diagnostics tool in order for the data to be actionable. Passive data collected by wearables and sensors also are very informative and may be of service in post-market studies that shed light on a specific disease. These types of apps allow for swift identification of an issue and a timely solution, which not only improves patient compliance, but also the patient experience overall.

While the patient's experience is first and foremost, it is important to note how technology can help a study run smoothly, not just for the patient, but also for clinical research staff. Advanced platforms can be uniquely customized to meet the study staff's needs. Imagine a platform that features study-specific apps, allowing for precise modifications to your ongoing study. The data collected are as distinct to your study's goals as possible. This means actionable data (e.g., analytics, metrics) that can help improve compliance. For example, let's say a patient's heart rate is too low. A customized solution can identify the issue in real time and then automatically alert a physician and/or investigator to notify the patient and prompt them to take the appropriate next steps.

For clinical research staff, solutions should automate their required, routine tasks as a key benefit. Finding the right platform allows clinical research staff to log into systems and efficiently access reports that are actionable for them. Examples of beneficial automation includes tasks like finding clinical trial kit management solutions and managing drug supplies for individual sites. Customized solutions can be used to upload data into the system and automate which kit is for which patient or which location has what type of kits—saving time on routine tasks means saving money, but more importantly, it allows for increased time spent on individual patients—again increasing the patient experience overall.

A Patient-Centric Approach Improves Patient Retention

With a focus on patient retention and compliance, finding solutions with dedicated patient concierge services is highly beneficial. Key components of effective concierge services include benefits such as the ability to call and check on patients, enter data on their behalf, and even ship necessary items directly to their homes.

Every trial is unique. Many sites, as we've discussed, are actively taking large steps in order to move toward DCTs and remote patient monitoring. Some sites are moving toward a hybrid (onsite/offsite) clinical trials model, whether permanently or as a “stepping stone” on the way to a completely decentralized model. Hybrid trials still require an in-person visit—whether onsite or in the patient's home. Many companies have taken steps over the last two years to push the limits of their technologies in order to better support the clinical research enterprise and meet the needs of any clinical study. When addressing a hybrid model, these requirements may include identifying the right level of in-home services.

One way to meet the challenge is to cultivate a network of nurses and healthcare professionals who can be assigned on an on-call basis to perform wellness checks and other in-home patient services, collecting data at visits while ensuring compliance. By offering staffing solutions in addition to technological solutions, companies can optimize themselves to be full-service, regardless of a specific clinical trial's design.

Giving patients more than one simple way of collecting data that doesn't add to the “laundry list” of life's never-ending chores is the way to improve patient retention. The most patient-centric approach a study staff can take is to implement the use of wearable technology, connected devices, and in-home sensors that can also be tailored to a patient's native language—ensuring a patient clearly understands what tasks need to be completed in order to be compliant.

Effectively Using Technology Makes DCTs Successful

The technology solutions have been out there for almost a decade. We could focus on the negative climate or the limitations that currently exist, or we can stay focused on the end-goal of

designing more hybrid and decentralized clinical trials, pivot, and adapt to meet the industry's needs and demands.

I and my staff chose to pivot to meet the new needs of clinical researchers at large. We have focused on the positive steps we have made, and worked to improve technologies and devices that we were already offering and working with. We have taken the outlook that, despite our struggle to keep moving forward even in the most difficult of times, we can continue to innovate.

Now, we must keep leveraging new and improved technologies, whether a new version of an Apple Watch and its updated apps, for example, or the “next best thing” that comes along in the near future. Our goals need to always be centered on patient care. We strive to create an environment of adaptability in order to increase patient diversity and make the DCT model the “new normal.” We and our colleagues at large have never forgotten that we are driven by a deep-seated and profoundly personal desire to help save patients' lives—one clinical trial at a time.



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OVER THE TRANSOM

Winning Strategies Help Map the Way to Modern Trials

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“There are two sides, two players. One is light, the other is dark.”—John Locke



First off, an admission that when John Locke, played by Terry O’Quinn, delivers the above line in an early episode of the late, great television series *LOST*, he is explaining the rules of backgammon to another character, not chess. However, chess, with its opposing armies, fits my mental image of what this column is about more closely than backgammon and I’m charge here, so what I say goes—right? Right.

The stark symbolism of chess, and even older games of a similar nature (see [senet](#), for example), must go back nearly as long as humans have been playing games. The notion of life and competition and our relationships to strangers being boiled down to light versus dark, good versus evil, us versus them—it’s not just buried in our subconscious. It all too often comes out to play in arenas of business—drug and device development, for example—where, yes, one expects healthy competition amongst the inventors and investors, but perhaps greater breakthroughs of real benefit to the masses could come from paying less attention to the scoresheet and more to the end-users.

This column, then, presents excerpts from announcements by various companies and sources of information (no endorsements implied) of new developments in software and service platforms one can imagine arising from strategic sessions that had more than just a “beat the other guy” mentality going on in them. I think it all goes to show that the more the stakeholders in the clinical research enterprise can foster the “we’re all in this together” attitude, the more wins we will all chalk up as we map the way to modern trials for the sake of better health and longer life for all.

Putting Patients in Control of Trial Technology

mdgroup, a provider of healthcare technologies and personalized clinical study services, [announced](#) in May that it is “transforming the clinical trial ecosystem with the launch of its enterprise solution,” known as Primarius3. The solution is intended to improve how patients, sponsors, sites, healthcare practitioners, and medical distribution centers connect through an integrated platform serving as a “central information hub and seamless integrated experience for site and home visits, hybrid services, compliant travel, expense/stipend management, and medical supply distribution, significantly reducing the [administrative] burden for all involved.”

According to the company, new technology places the patient in full control of how they receive and interact with all of their trial information, which “facilitates greater access to clinical trials, enhances patient engagement, and significantly reduces dropout rates,” as well as benefits the way sponsors and healthcare providers interact with information. The company adds that eventual updates will include home visit information for decentralized clinical trials, while also allowing management of medical supplies. “A rapid, fully integrated and automated [artificial intelligence (AI)] patient and site payment and reimbursement system is also due for release later this year,” **mdgroup** notes.

The Next Generation Arrives...

Emmes, a contract research organization, [introduced](#) to market its third-generation version of Advantage eClinical at the Society for Clinical Trials meeting in San Diego in May. The product’s cloud platform is now available as a standalone software product after undergoing more than two years of development. “The system has been specifically designed to provide fast study builds, greater flexibility, and insights to clinical trial sponsors of all sizes,” the company says, including apps for study design, electronic data capture, randomization and trial supply management, patient-reported outcomes, safety data and reporting, risk-based monitoring, source data verification, and specimen/shipment tracking. It will be offered as part of combined packages with data consultation services, or simply as a standalone software product. Emmes says the product has supported more than 1,000 trials, for nearly one million patients in more than 70 countries, spanning more than 31,000 clinical trial sites.

Trends in the Global Drug Discovery Software Market

According to [a recent overview](#) of the global drug discovery software market, the market is driven by an increasing research and development spend and pipeline, expanding scope and scale, increasing stringency of testing and regulations, growing number and size of biotechs, need for greater cost efficiencies and reduced time to market, and a move toward web/cloud-based software. The market is niche and growing rapidly, driven by the rising pressure on pharmaceutical and biotechnology companies to cut costs in the research and preclinical stage of

drug development, reduce timelines, and improve transparency through deep learning software tools.

The overview goes on to note how the life sciences industry is increasingly recognizing the benefits offered by big data and AI/machine learning in drug discovery, and that biologics are expected to experience strong growth in the drug discovery phase; 50% of drugs currently in the preclinical phase are biologics. To leverage growth opportunities, companies are entering/expanding into biologics software space. The drug discovery software industry is slowly moving toward cloud-based solutions, as these can address most of the aforementioned issues with on-premise installations and provide quick deployment, minimum upfront costs, high flexibility, and scalability at affordable rates for even small and medium size pharma/biotechs, academic research/universities, and contract research organizations.

Focus on Cancer Patient Clinical Trial Recruitment

In June, Trialjectory, an AI-powered decision-support platform for patients, healthcare providers, and pharmaceutical companies, [presented](#) a poster on cancer patients' clinical trial participation at the American Society of Clinical Oncology (ASCO) Annual Meeting. The poster highlighted clinical trial registration and participation for patients using the platform, showing significantly higher engagement and enrollment rates compared to reported national averages. The platform was highly effective at offering patients and their doctors access to relevant clinical trials for a patient's exact diagnosis, which directly converted into higher referral and enrollment rates across different cancer types.

According to the company, the platform “helps patients to understand all of their available treatment options” so that, equipped with this knowledge, they “can then make more informed decisions about their healthcare in partnership with their oncologists.” Trialjectory adds that it uses AI and machine learning to efficiently sift through vast amounts of information that an individual doctor or patient cannot accomplish on his or her own, to successfully match patients to the most relevant clinical trials.

