



Clinical Researcher

The Authority in Ethical, Responsible Clinical Research

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What's Keeping You Up at Night?

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Clinical Researcher

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EXECUTIVE DIRECTOR'S MESSAGE

Strategies in the Face of Workforce Challenges

Susan P. Landis, Executive Director of ACRP



Whether it be the “[Great Resignation](#),” “[quiet quitting](#),” or reluctance to RTO ([return to office](#)), clinical research–related organizations share in such woes alongside the rest of the employment market.

What’s a leader to do? Fostering [flexibility](#), [camaraderie](#), and [diversity](#) may seem like obvious places to start in terms of de-stressing and rewarding your talented teams. Beyond that, ACRP is taking steps to help our members attract people who are “on the outside looking in”: reducing and removing barriers to entry-level

employment and cheerleading for wider acknowledgment of clinical research as a true profession. Consider some of your resources from the Association, as summarized below.

Reducing and Removing Barriers

Members of [ACRP’s Partners Advancing the Clinical Research Workforce](#) say two key challenges are threatening development of the clinical trials sector. First, they lament that there is a lack of awareness of clinical research as a profession (more on that later)—even after the publicity it gained during COVID-19 vaccine development. However, the consortium highlighted a second, incontrovertible barrier: the default prerequisite for a specific number of years of experience—very frequently two years—in entry-level job descriptions.

In response, the Partners have published a new white paper, “[Barriers to Bridges: Addressing the Urgent Need for a Diverse, Research-Ready Workforce Within the Clinical Research Profession](#),” exploring the growing workforce shortage in clinical research, its root causes, and disruptive ways to turn barriers into bridges.

Ready to Go

With an eye on a growing global workforce shortage, ACRP also recently announced an innovative training program that helps to accelerate the introduction and onboarding of new entrants into the clinical research profession. [ACRP's "Early Talent Training Program™"](#) is a first-of-its-kind, comprehensive curriculum that prepares candidates and lateral movers for work involving the setup, management, regulation, support, and reporting of clinical trials. The three-week training program allows sites, contract research organizations, academic and health institutions, and sponsors to more quickly onboard those who are new to clinical trials and who have the right skills to succeed in the profession.

Cheerleading for the Profession

Meanwhile, the problem with being a cheerleader for clinical research begins with its lack of recognition as a tried-and-true profession that is acknowledged and tracked by the Bureau of Labor of Statistics, as is, for example, the nursing profession. With this type of recognition, we would have more data and a better understanding of the industry's needs.

One resource for tackling this issue is ACRP's ["Ready, Set, Clinical Research!™"](#) outreach effort, designed for flexible use by career advisors, recruiters, employers, and other stakeholders with a vested interest in the growth and diversification of the clinical research workforce. Using carefully crafted, impactful messaging intended to influence both hearts and minds in your community, this online kit features emotive, personal stories from patients and clinical research professionals to emphasize the people-centered nature of clinical research and foster a sense of excitement, inspiration, and curiosity.

Be Our Guest

If you find yourself struggling to form a coherent strategy for facing any of these challenges, I encourage you to take advantage of the advice, knowledge, and creative tools ACRP has to offer; to share your feedback on them with us; and to let us know about your organization's own successful pathways for tackling any other aspects of the chaos of our times.



PEER REVIEWED

Diversity, Equity, and Inclusion in Patient Recruitment and Retention

Kate Schroeder; Seth Palmer, MBA, CDMP



It is crucial to improve diversity, equity, and inclusion (DEI) in clinical trials for the health and well-being of everyone. Health disparities and inequities among marginalized communities reflect the institutional structures that impede communities from accessing healthcare and clinical studies. There are many steps the industry can take as it strives to improve upon DEI, including increasing diversity among leadership and physicians, destigmatizing clinical research, translating recruitment and retention materials to multiple languages, focusing on DEI when building out protocols, and more.

The points outlined in this article offer some guidance for the clinical research industry but are not comprehensive. Rather, the suggestions highlight the importance of DEI in clinical research and further the discussion toward meaningful change. Moreover, any claims made about the experiences of people of color, LGBTQIA groups, socioeconomically disadvantaged populations, or people with disabilities are not representative of entire communities. Additionally, this article does not address intersectionality due to the lack of data around patient populations belonging to multiple groups.

Background

Clinical research is the backbone of healthcare advancements, but historically, clinical trials have lacked diverse representation. The process of patient recruitment and retention, the demographic makeup of the healthcare industry, and the biopharmaceutical industry as a whole need impactful change.

Age, family medical history, environmental conditions, physical and mental well-being, and many more factors can potentially impact the effects of certain medications and treatments. Moreover, clinical trials are often the first chance to receive a new, potentially life-changing or life-saving treatment. Therefore, patient recruitment and retention campaigns and clinical trial processes must be appropriately inclusive of everyone.^{1} With many elements of diversity, the clinical research industry must improve inclusivity across all identities, including for racially or ethnically marginalized groups, LGBTQIA communities, socioeconomically disadvantaged populations, persons with disabilities, people of all ages, and other marginalized groups.

Currently, communities of color are largely underrepresented in clinical trial participant populations. For example, according to the U.S. Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research 2020 report, people of color made up 25% of the participant population of clinical trials.^{2} As reported by the 2020 U.S. Census, people of color make up approximately 37.1% of the U.S. population.^{3}

Further, certain conditions and diseases disproportionately affect specific groups of people. For example, there are higher incidences of multiple myeloma, colorectal cancer, triple-negative breast cancer, and prostate cancer in African Americans; of gastric cancer in Asian Americans and Pacific Islanders; and of cervical cancer in Hispanic and American Indian/Alaska Native women, yet these communities are underrepresented in clinical trial participant populations.^{4}

Ultimately, clinical studies are an opportunity to obtain new, groundbreaking treatments, which is why it's important these studies are accessible to everyone.

Historical Context and Present-Day Biases

The first step in finding solutions is understanding the inequities marginalized groups face, especially Black and Indigenous people, LGBTQIA communities, and lower socioeconomic populations. For example, there is a major lack of trust between Black Americans and the healthcare system due to historical exclusion and exploitation and present-day health inequities. Some of this sentiment is connected to the revelation that, from 1932 to 1972, researchers in the now-infamous Tuskegee syphilis clinical trial misled and withheld treatment from 399 Black men with syphilis. These people were told the researchers would cure syphilis, but the researchers never intended to treat them.{5}

Black Americans are less likely to receive the same quality care white, cisgender, heteronormative people receive.{6} According to a recent study, Black Americans are 22% less likely than white Americans to be treated for symptoms of pain.{7} There are many factors that contribute to the health disparities Black Americans and other communities of color face, including, but not limited to, systemic and institutional racism and socioeconomic barriers.

Additionally, LGBTQIA communities experience biases within the healthcare system. According to a recent survey, 37% of transgender respondents and 33% of nonbinary respondents reported having avoided medical treatment for fear of discrimination.{8}

There is a need among healthcare professionals and the clinical research industry for more cultural humility and biases training regarding race, ethnicity, sexual orientation, and gender identity. Moreover, people of a lower socioeconomic status encounter increased financial barriers to clinical trial participation. Indeed, while most clinical trials offer compensation for participating, the financial incentive for participation rarely, if ever, outweighs the financial cost of joining a trial for those who are hourly employees or need to pay for transportation. The cost of transportation, lodging, and time away from work can make participation in a clinical trial seem infeasible.

Another impediment to participation is the costs study participants must cover for childcare, pet care, or other domestic responsibilities, which may be an obstacle for people who are financially disadvantaged. Thus, the financial cost for joining a clinical trial disproportionately affects people experiencing economic disadvantages.

Manifold Solutions for a Complex Topic

While the FDA and the clinical research community are taking many steps to increase diversity and address inequities, the potential solutions are—and need to be—manifold, given the complexity of the issue.{9} One solution to increasing diversity and inclusivity in clinical research is improving diversity and inclusivity among healthcare professionals and those involved in healthcare research. Nationally, people of color make up only 14% of physicians, and 98% of senior managers in healthcare organizations are white.{10}

LGBTQIA members also have very little representation in healthcare and research; according to a recent study, approximately 8.8% of medical students graduating in 2019 identified with the LGBTQIA community.{11} More work needs to be done to include more people of color, LGBTQIA persons, and people of other underrepresented groups in leadership positions and patient-facing roles. As the healthcare industry continues to strive toward inclusivity, participants will feel a sense of trust and safety with physicians who have similar lived experiences to their own. Moreover, individuals communicating directly with participants should be trained in cultural empathy and biases when interacting with people of identities different from their own.

Another solution to increasing diversity in clinical trials is destigmatizing clinical research. To address clinical trial stigmatization, the clinical research community must build trust. That starts with the messaging around clinical trials. When recruiting patients for clinical trials, there needs to be a relatable voice speaking to potential participants through direct communication, posted flyers, social media, and other paid advertising to reduce mistrust and increase the understanding of trials and their value. Recruiting communication should be casual and use colloquial language, and the imagery must be appropriately representative of the patient population.

Visible partnerships need to be fostered over time between healthcare research organizations and underserved communities through community and advocacy group partnerships. For example, the Biden administration partnered with local organizations and leaders in Black and Brown communities to improve vaccination numbers. According to a recent analysis by the Kaiser Family Foundation, “the racial disparities in COVID-19 vaccinations have narrowed” since the

start of the Biden administration's plan.{12} For clinical studies, a similar plan may be beneficial when building trust with marginalized groups.

Additionally, research sites might consider incorporating an avenue for patients to provide feedback. According to The Deloitte Center for Health Solutions' study, respondents noted they would appreciate and use a platform to provide anonymous feedback for their healthcare professionals.{13} In brief, there are many avenues to build trust between marginalized communities and healthcare professionals.

Further, there is still a lot to be done to increase accessibility. When pharmaceutical and biotechnology companies are selecting research sites, it's important to consider the site's location and the ease of travel or even parking for those with limited access to transportation. Also, wheelchair ramps, highly visible signage, and knowledgeable check-in staff can help with early-stage participation and participant retention throughout a clinical trial.

Lastly, biopharma businesses might consider implementing more research sites with researchers who speak multiple languages. It is also important to consider altering research sites' hours to include nonbusiness hours for participants who cannot skip work due to financial or family obligations. Again, the issue and solutions are manifold, but it is a positive sign that many people in the clinical research industry are asking themselves and their companies how increases in diversity, equity, and inclusion in clinical trials can be brought to life.

Currently, the demographics gathered for study participants are nationality, race/ethnicity, age, and gender (and only male or female). To understand the industry's progress, there must be a concerted effort to implement a comprehensive survey for all identities, especially to unpack intersectionality. With these data, the industry will be better prepared to improve inclusivity for everyone.

Conclusion

When it comes to people's health and well-being, swift and impactful change is needed to save lives and reduce disparities in health across all communities, particularly for those who are disproportionately affected by health inequities. Fortunately, the healthcare and clinical research industries are on the path to addressing the issues of inaccessibility and building trust.

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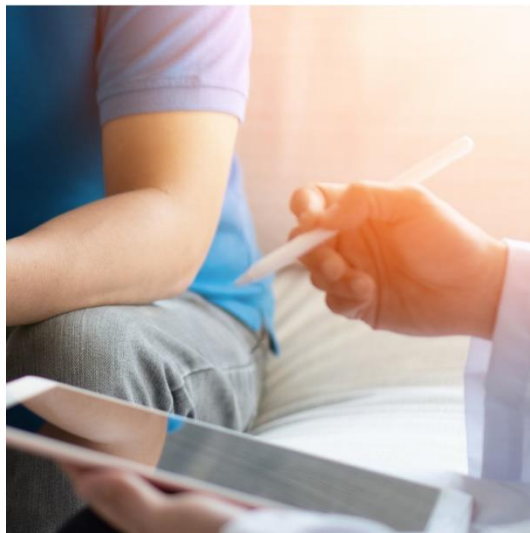
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How Decentralized Clinical Trials Can Transform Oncology Treatment Research

Krystyna Kowalczyk; Jane Myles



The pandemic accelerated the adoption of decentralized clinical trials (DCTs) for medical and pharmaceutical research. DCTs allowed trials to be conducted virtually after early COVID-19 travel restrictions and physical distancing caused site-based trial starts to [plunge](#) 50% from January to April 2020. As a result, we learned that patients prefer to visit convenient locations for their care, and our industry can leverage existing services and resources to make clinical research possible at these sites.

Fully remote or hybrid trials conducted from a patient's home or local trial site (such as the office of a patient's provider) offer several benefits to clinical research organizations (CROs), pharmaceutical companies, and medical device makers. The benefits of DCTs include greater convenience for participants, faster recruitment, the ability to attract a more diverse cohort, and lower dropout rates because travel-related burdens are eliminated.

DCTs also can help long-term clinical trials gather follow-up data from patients well after the active phases of the trial have concluded. This is particularly important in the field of oncology, where trials typically track patient survival long after study treatment has stopped, often over many years. While oncology has been slower to adopt DCTs than other medical specialties, many oncologists realize this type of service could be a game-changer for cancer research and treatments.

The clinical research field is more crowded than ever, even the largest sites have limited capacity and struggle with maintaining an adequate level of staffing. Compounding this shortage of resources and staffing at large medical research centers is the increasing number of innovative studies around long-term immunotherapies; as part of regulatory requirements, these studies require extended follow-up with participants.

Another challenge oncology researchers face under the traditional site-based clinical trial model is the ongoing struggle to attain patient diversity in trials. The U.S. Food and Drug Administration emphasizes the importance of patient diversity and the democratization of research, but when trials are repeatedly conducted at a small number of sites, they draw from the same geographic and demographic pools. Ultimately, lack of patient diversity has a negative impact on drug development because the products aren't being tested on all types of patients who might need them.

How DCTs Can Help Oncology Trials

Each one of these challenges can be overcome through the decentralization of clinical trials. Using DCTs for oncology clinical studies provides many clinical and operational benefits to CROs, pharmaceutical companies, and device makers. DCT providers and platforms can help trials cope with site-based resource and staffing limitations by enabling activities to be conducted away from a single trial location via the use of remote software and staff to collect data outside the research center.

DCT platforms and providers are ideal for conducting follow-up procedures required under the trial protocol, such as filling out quality-of-life questionnaires and collecting biometric data. These types of activities don't have to be performed at a major research center by clinicians with advanced skill sets to meet compliance requirements. By using a DCT model to gather follow-up data, the leaders of academic research centers can focus their scarce resources and expertise on a wider number of clinical trials driving new opportunities for the most cutting-edge oncology treatments. This opens additional modalities for clinical trials beyond the traditional site-based model and allows academic centers to expand their capacity to do innovative research while using clinical resources most efficiently.

Further, DCTs can help ensure a seamless transition from one trial modality to another. For example, a study involving advanced cancer cell therapy may start at a hospital or major research center and initially require careful oversight by a physician. Patients in the study may be tracked closely for a short time after the clinical phase of the trial and then less intensely over a longer period. This may also allow patients seeking the most advanced therapies to travel to academic centers for the induction of that therapy, but then to be followed for safety and efficacy with their own personal oncologist within their community.

As an extension of that thinking, it is possible to leverage DCT technology to bring trials to the patient's personal physician using means of telemedicine, home health nursing, remote devices, and other DCT technologies that support local physicians who may be new to research. This can be done under the supervisory watch of an academic lead principal investigator (PI), with a central lead PI for remote physicians, or even with the local physician acting as the PI for their own institution. In any case, the ability to bring the best clinical trial to each oncology patient is ultimately where DCTs in the oncology space will evolve.

Bringing Research to the People

Most patients want to go where they are comfortable and where it is convenient. DCTs leverage this patient need by supporting participation in clinical trials and follow-up in community locations (such as their primary care provider's office) or even at home. Bringing the research to people in their communities and homes is the definition of patient centricity.

Consider the example of a cell therapy program. The opportunity to receive these cutting-edge therapies is limited to a subset of large research institutions. Patients looking for these kinds of innovations will often have to travel to the cities where therapy is available. The therapy itself tends to be relatively quick. Patients will come in for induction and treatment and perhaps have a period of follow-up. However, the intent of these programs is to provide a long-term immunological effect. That means these patients are followed for years rather than months. The ability to transition these programs from institution-based follow-up to regional review of safety profiles can clearly expand access and thereby accelerate enrollment.

Applying the same concept to programs looking at long-term progression or survival can often provide a similar type of benefit. Innovative programs can be closely monitored for initial treatments and responses including adverse reactions, and patients can then continue to get a high level of care within their community.

By no means is this model applicable to every clinical program, but as an industry, we would be well served to challenge ourselves regarding the implementation of clinical programs. We have already entered an era where the concept of decentralized care is becoming normalized. It's now necessary for our community to expand our thinking, embrace concepts of true patient centricity, and build an infrastructure that will allow us to accelerate the evaluation of innovative compounds changing the lives of patients while supporting their ability to remain engaged in their established social circles.

Conclusion

Enabling long-term clinical trials through multiple modalities such as DCTs would benefit oncology patients, pharmaceutical companies, academic institutions, and clinical researchers. DCTs offer a digital platform that enhances clinical resource and skills allocation, improves participant recruitment and retention, increases compliance, and reduces clinical trial costs.

In addition, DCTs can be a catalyst for oncology research breakthroughs that otherwise wouldn't be possible through traditional site-based trials. Such clinical and pharmaceutical innovations can save and improve lives.



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OPINION

With a Reinvigorated Focus on Vaccine Research, Why Are We Still Using Dated Approaches?

Musaddiq Khan, MBA



The pace of development for new medicines has traditionally been slow and burdened with lengthy enrollment, conduct, and analysis timelines. However, COVID-19 was a catalyst to adopt novel approaches to drug development that have harnessed technology to create new, accelerated processes for conducting clinical trials. Technology-enabled hybrid and decentralized clinical trials (DCTs) are now moving from the periphery into starring roles across many areas of research—with a notable exception. Though

vaccine developers rapidly adopted DCTs during the pandemic, today there is a surprisingly slow uptake of novel technologies across vaccine studies compared to other therapy areas.

Background

Only 17% of vaccine trials today use some form of decentralization,{ 1 } even as nearly nine in 10 sponsors use decentralized technology to support at least one of their clinical trials, according to the [2022 State of Clinical Trial Operations Report](#).{ 2 } This is ironic, given the importance of speed to vaccine development, which is often initiated to urgently prevent a pandemic or stop the spread of a highly infectious disease variant.

At the same time, vaccine clinical trials are being re-prioritized by manufacturers, who are historically less incentivized to develop vaccines for diseases that eventually vanish. From an economics perspective, preventative vaccines are durable goods with long-term effects in contrast to therapeutics, which are ongoing treatments purchased repeatedly. As [The Economist](#) summarizes, “profits in vaccine making are low.”{3} This may be one reason that between 2014 and 2018, the U.S. Food and Drug Administration (FDA) approved only nine vaccines, compared to 213 therapeutic drugs.{4}

Public policymakers have a different perspective, however, as they say vaccines ultimately save money. According to research from the [Decade of Vaccine Economics \(DoVE\) Project](#), every U.S. \$1 invested in vaccine programs returned an estimated \$20 in saved healthcare costs, lost wages, and lost productivity.{5} “It costs less to prevent disease than it does to continuously treat disease,” said Marty Anderson, chief strategy officer at Meridian Clinical Research, which specializes in vaccine trials. “The economics of missing work, childcare, [and] hospitalization far outweighs the development costs.”

Bottom line, vaccines are vital to humankind’s survival. Between [2020 and 2030](#), vaccination programs against 10 pathogens in 98 countries are projected to save 32 million lives—the vast majority will be children under age five.{5} Aggressive vaccination campaigns inspired by the pandemic and fears of future COVID-style lockdowns have prompted greater investment in vaccine development across both public and private sectors. GlaxoSmithKline (GSK) now has more than [30 potential new vaccines and medicines](#) (including preclinical assets) in 13 high-burden infectious diseases{6}; Merck & Co. makes vaccines for 11 of the 17 diseases on the Center for Disease Control’s recommended immunization schedules{7}; and Pfizer is [investing \\$470 million](#) into its vaccine research facilities at its location in Pearl River, N.Y. to develop a new portfolio of mRNA vaccines.{8}

Fear of Change vs. Grounded Logic

Logic points to a convergence of vaccine trials and a DCT model today, but logic isn’t sticking while fear of change is.

“Vaccines are a niche business,” said Steve Clemons, senior vice president of client delivery for Velocity Clinical Research. “Organizations that have professionalized vaccine trials believe they already know best practices and don’t want anything slowing them down in running these high-volume trials. They don’t want to add steps to the trial, fearing any additional layers of complexity could delay enrollment. For instance, DCTs are perceived to bring integration challenges, device provisioning concerns, and regulatory considerations, so sponsors and sites stick to what they know—even if that [means] aging, paper-based processes.”

In reality, hybrid and decentralized trials can help to speed trials. The DCT model has proven to reduce timelines over traditional trial processes through faster patient recruitment and enrollment and other efficiencies. In fact, a new [study](#) from the Tufts Center for the Study of Drug Development shows that DCTs reduce development cycle times, lower clinical trial screen failure rates, and have fewer protocol amendments. These benefits yield net financial benefits ranging from five to 13 times for Phase II and Phase III trials, equating to roughly \$10 million and \$39 million in return on investment, respectively.{9}

Vaccines are the cornerstone of the management of emerging and re-emerging infectious disease outbreaks and are the surest means to defuse pandemic risk. The faster a vaccine is deployed, the faster an outbreak can be controlled. Following a traditional research and development pipeline, it takes between five and 10 years to develop a vaccine for an infectious agent. The standard vaccine development cycle is not suited to the needs of explosive pandemics. DCTs, however, can shorten that cycle and make it possible for multiple vaccines to be more rapidly developed, tested, and produced.

Real-World Benefits and Public Perception

Consider the speed of COVID-19 vaccine trials, many of which leveraged digital technologies. These vaccines were available for public use in seven months from the start of clinical trials in a record-breaking, cross-stakeholder response to rapidly spreading, unchecked viral infections. Rather than go backwards, the industry needs to continue to build on the progress gained in the early days of the pandemic and make hybrid trials instrumental in vaccine development.

“At the same time, we must balance speed with public perception—or misperception—that speed equals cutting corners,” added Anderson. “We should embrace faster, decentralized approaches in vaccine development while working in parallel to build public confidence.”

Katie Moureau is a patient advocate with five boys, ranging in age from 13 years to 22 months, including a son who has respiratory vulnerabilities. “Decentralized vaccine studies are beneficial not only for my 7-year-old, but all those who have immunocompromised systems. More efficient vaccine trials can influence whether participants continue or drop out of a trial, preventing unnecessary delays while protecting those who are vulnerable.”

Templatize to Speed Vaccine DCTs

Vaccine trial protocols are relatively homogenous from trial to trial, taking place over a relatively short period of time and involving a high volume of participants. For all their similarities, vaccine trials are ripe to be templatized to speed set up and analysis.

“A typical Phase III efficacy trial can include upwards of 40,000 participants, so the logistics of managing that many individuals and tracking their post-vaccination status, including diary entries, is one of our biggest challenges,” explained Anderson. “Vaccine trial protocols are somewhat predictable—administer the vaccine, monitor the participants, record typical reactions or events, and potentially monitor the participants over the course of ‘a season.’ DCT technology could help monitor such a high volume of patient-reported outcomes and even automate alerts or reminders for better data collection. So while the trial set up is fairly simple, it is crucial that no events are missed because, especially with efficacy trials, every incidence of infection can be important to trial outcomes.”

Clemons added, “Delays are always a concern with vaccine trials, which typically need 30,000 patients versus 3,000 in a therapeutic trial, and regulators want proof of population representation. Ensuring a diverse participant pool is very time-consuming, but DCT technologies can really speed the process of patient recruitment and consent while expanding geographic access to more demographics.”

DCT solutions that templatzize best practices common across most vaccine trials not only speed the process, they also allow for higher quality data to be collected from patients without the burdens of travel and reviewed in real time by investigators. For the same reason, DCTs also expand access to vaccines to more regions—particularly important to vaccine-naïve parts of the world.

Early data show a pre-packaged vaccine DCT-in-a-box reduces study startup time by at least 50%--from 12 weeks to five weeks or less. Speed, access, and data quality are all critical for vaccine trials. By codifying the most common elements across vaccine trials, compliant DCT platforms can minimize the need to do a ground-up build for every new vaccine study.

“As we know, one of the pain points for study participation continues to be hesitancy based on perceived disruptions to our daily lives,” said Allison Kalloo, MPH, a minority patient recruitment specialist and founder of Clinical Ambassador. Kalloo, who is also a vaccine trial participant and member of Medable’s Patient Advisory Council, adds, “Vaccine trials can benefit from a prepackaged solution that can ease access and compliance while communicating transparently and better managing expectations—especially for underrepresented communities of color.”

Leave Room for Flexibility

While pre-packaged DCT solutions enable fast study startup and scalability by standardizing core capabilities required in a vaccine trial, it’s still important to allow for flexibility to accommodate different trial designs. For instance, different vaccine trials may need additional visits or unique physical assessments. The good news is that one of the decentralized model’s trademark benefits is its built-in optionality for all stakeholders, including participants, sites, and sponsors/contract research organizations, while ensuring that the goals of participant safety and collection of robust, reliable data are not compromised.

“A standardized DCT platform that facilitates efficient, one-on-one communication between participants and site staff would be particularly beneficial in vaccine trials, especially considering the sheer volume of participants,” concluded Anderson. “Participants put their trust in the site staff and if you take that away, that hurts everyone. But if you provide a technology that not only offers greater efficiency but also enables better communication, it’s a win-win.”

Conclusion

It's time that we address and acknowledge the unique challenges and significant responsibility that this new era of vaccine research brings to fighting infectious disease. By applying a modern, technology-driven approach to such vital research, the industry can move faster and may even be able to get a jump on the next pandemic.

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The Business Case for Patient Experience

Scott Gray



For some patients, participating in a clinical trial may be the only way to secure treatment when no other approved options are available. Others altruistically choose to participate in clinical trials to advance science and help future patients who may be suffering from the same disease. In either case, there is a real human need contingent upon clinical trials meeting their targeted enrollment, retaining participants, attaining crucial milestones, and resulting in successful outcomes. Yet, despite

the best efforts of study stakeholders, recruitment and retention continue to be challenges for the industry and the most significant cause of trial delay.

Two-thirds of clinical trials fail to enroll enough patients to conduct the trial effectively,{1} and 85% of trials fail to retain enough patients to complete the study.{2} Even after patients are successfully enrolled, clinical trial coordinators face an uphill battle in retaining patients for the duration of the study; dropout rates typically exceed 30%.

Recruitment and retention problems have a cumulative effect, often resulting in trial delays. Only 6% of clinical trials finish on time, and 80% are delayed by at least one month.{3}-Delays negatively impact study costs and future sales, causing the industry potential losses of between \$600,000 and \$8 million per day.{4} The toll of these delays on humans, however, is immeasurable.

Despite these challenges, pharmaceutical sponsors and clinical research organizations (CROs) are working to increase patient recruitment and retention rates and to improve trial performance using patient-centric engagement strategies to elevate the patient experience.

The Patient's Role in Clinical Trial Return on Investment (ROI)

The cost of developing a new drug is enormous. An often-cited study by the Tufts Center for the Study of Drug Development^{5} calculated an average of \$2.6 billion, while a study in *JAMA Internal Medicine*^{6} suggested an average of closer to \$1.3 billion. Trial costs vary greatly, of course, driven by several factors, including the number of patients required to establish a treatment's efficacy and the number of site visits needed for the treatment to be effective. At one time, the median cost of clinical trials for new drugs seeking approval from the U.S. Food and Drug Administration (FDA) was estimated to be \$19 million.^{7}

In comparison, trials with more than 1,000 patients had an average cost of \$77 million,^{7} and pivotal (Phase III) studies for new drugs approved by the FDA cost a median of \$41,117 per patient.^{8} According to one report submitted to the U.S. Department of Health and Human Services, the range of requisite investment for clinical trials and each patient enrolled in a trial is as broad as the number of studied diseases.^{9}

However, what if we considered these figures from another angle: the pharmaceutical industry cannot exist without patients. Rather than looking at patients as a cost to clinical trials, why not consider the value of their participation?

For example, look closely at the commercialization of a well-known drug treating multiple sclerosis. The drug has been on the market for five years, is prescribed often, and the sponsor has realized substantial revenue and ROI from their clinical investment, with total earnings of approximately \$17.5 billion at the time of this article. The clinical trials supporting the drug's initial FDA approval involved 1,656 patients.^{10}

In other words, each trial participant who enabled the drug to get to market resulted in more than \$10.5 million in revenue.

Much of a drug's success can be attributed to its clinical trial participants, without whom the drug would not achieve commercialization. The revenue estimate is a rough calculation, but the figure illustrates the value of patient participation and the potential return on investment for trial completion. Of course, the improved quality of life for the patients who gain access to a novel treatment is immense.

The stakes are considerably higher in trials for rare diseases{ 11 } (defined in the United States as those affecting less than 200,000 people), with fewer eligible patients and a greater need to keep patients enrolled and engaged through trial completion. Patient scarcity exponentially increases the value of rare disease trial participation.

The rarer the disease, the more significant the potential is for smaller patient populations with clusters in disparate geographic regions. Thus, the travel burden associated with these trials typically increases, as trial sites are generally restricted to specific, well-known institutions in large urban centers. This dynamic also increases the threat of participants dropping out and not completing the trial—a danger greatly exacerbated when the pool of eligible patients is smaller. These factors significantly increase the costs associated with rare disease trials.

Drug manufacturers must recoup their research and development investments and secure drug approvals to help patients and their bottom line. The importance of employing patient support strategies to enhance retention is critical. The patient experience is pivotal to completing clinical trials and sits directly at the intersection of the humanitarian mission and business motivation for drug development.

Benefits of Patient Centricity

For CROs and trial sponsors, understanding the patient experience is critical to advancing patient-centered trials. As our industry works to develop and define patient centricity in clinical trials, the overarching goal remains—to utilize the most effective tools to improve patient experience and deliver lifesaving treatments and life-enhancing products to market sooner.

Investing resources in patient experience programs benefits trial sponsors in several ways, including:

- Improving recruitment, retention, and diversity efforts: by reducing barriers hindering patients' willingness to participate and remain in a trial.
- Getting lifesaving and life-enhancing therapies to market faster: making day-to-day aspects of the trial easier for patients results in fewer delays.
- Obtaining better data: an improved experience results in less stress placed on patients, mitigating the potential impact of stress on the integrity of trial data.
- Decreasing the likelihood of trial deviations: this reduces the risk of not securing the requisite approval for a drug to reach the market.
- Engaged participants: when patients feel included and supported during a trial, they feel their contribution is valued.

Throughout 2022, the FDA is releasing a series of guidelines with recommendations for how drug development programs can incorporate patient voices.{ 12} The message is clear: prioritizing patients' social needs is equally important as caring for their healthcare needs.

The collective ability and willingness to put patient experience at the center of trial design is paramount to optimizing clinical trial outcomes. The industry is responding with patient-centric trial designs, involving patients earlier in the process and encouraging patient participation while mitigating risks and improving the quality of the research.

Outcomes improve when patients' needs are considered and incorporated into early trial protocols. One study found drugs developed with patient-centric processes were 20% more likely to launch than those produced without them.{ 13} Placing greater emphasis on patients' needs and concerns and improving communication results in increased patient satisfaction, reduced dropout rates, and a higher likelihood of trial completion.

The reasons patients drop out of trials range significantly and include fear, financial constraints, travel burdens, feeling underappreciated, health issues, work pressures, and more. Examining patient experience can offer insights into the many obstacles facing patients and caregivers.

Another benefit of patient experience efforts is the potential to lower participation barriers, resulting in enhanced patient diversity. Diversity among trial patients supports regulatory approval, as a high value is placed on enhanced diversity.{ 14}

Investing in Patient Experience

Understanding what creates a superior patient experience and prioritizing additional patient support as a strategic business objective offers an advantage in today's complex and competitive drug development landscape.

Clinical trial teams can focus on what patients deem essential to their experience to generate better trial performance, such as faster recruitment or higher patient retention rates. In other words, the greatest returns come from addressing what matters most to patients.

To identify opportunities to improve patient experience, trial sponsors should determine pain points or missed expectations through analyses of trial patients. Clincierge recently commissioned an independent study of patients who participated in clinical trials; our research partner found that 95% of patients say they have “seriously” considered dropping out because of travel-related challenges.^{ 15 } Travel is also a significant barrier to participant recruitment and a clear pain point for nearly all patients surveyed.

Patients traveling to clinical trial sites commonly express concerns about being comfortable through flights, coordinating wheelchairs once they have landed, and finding accessible bathrooms and ground transportation able to accommodate wheelchairs. Caregivers flying with a disabled patient require extensive planning and coordination to book hotels and adequate local transportation. Parents face additional expenses when traveling with their children when travel costs are not covered or only covered for the trial participant.

Ongoing travel to and from clinical trial sites can have a ripple effect on patients and their caregivers, who suddenly face the pressures of missed work (and subsequent loss of income), time away from home and family, increased childcare needs, and financial burdens of travel.

These complexities intensify for patients and caregivers in rare disease trials, which typically involve additional pressures of foreign travel such as visas, relocation, language translation, housing, and transport of medically fragile (often pediatric) patients. It is understandable why nearly all patients consider dropping out of a clinical trial at some point due to the many challenges associated with travel.

The good news is trial sponsors and CROs can help mitigate any negative impact travel could have on trial retention by employing patient-centric strategies and patient support services programs to assist trial participants in navigating travel and managing reimbursement. From the patient's perspective, these efforts are a leading consideration when enrolling or continuing their participation in a trial. In the aforementioned patient experience study, 100% of respondents said having a dedicated person to help them manage trial logistics was important. { 15 }

Providing patient support services throughout a clinical trial can minimize the additional pressures placed on patients and their caregivers to orchestrate trial participation. By employing patient care coordinators who manage logistics, including travel and reimbursement, patients and their caregivers can focus on the trial itself and the treatment provided, not the complicated logistics involved.

Conclusion

Patient retention and patient experience are inextricably linked. As the medical community sees the value in putting patient experience at the center of clinical trials, outcomes will improve for both patients and the industry. Improving patient experience expedites the process, making lifesaving and life-enhancing therapies available to more patients more quickly and allowing healthcare to maintain its original goal—caring for the health and well-being of patients around the globe.

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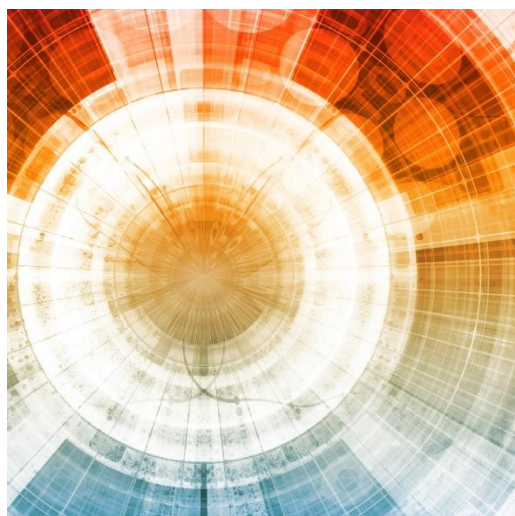


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SITES & SPONSORS

The Renaissance of Small Molecule Drug Discovery

Haydn Boehm, PhD



With biologics dominating headlines, one might be tempted to think that small molecule discovery is fading, or that there is little viable target and drug space left uncovered. This simply isn't the case. In fact, [small molecule drug discovery](#) is entering a renaissance.

In 2021, 62% of new drug approvals [were for small molecules](#), including new treatments for HIV, cancer, infections, heart and kidney disease, neurological disorders, and more. While market share may shift as biologics discovery grows, small molecules—both alone and as part of mixed entities—will undoubtedly remain reliable and cost-effective treatment options for a wide range of common conditions.

There is, in fact, target and drug space beyond what has traditionally been possible; but stagnated approaches to small molecule drug discovery just won't get us there. Innovation is key. Just as novel methodologies and technologies have propelled biologics from theoretical concepts into the realm of available treatments, so will they help deliver a second coming of small molecules. There is much potential to be realized in small molecule drug discovery as we see advances in screening technologies, target exploration, and computational methods, including artificial intelligence (AI).

However, barriers to innovation abound: rising costs, technology gaps, data management challenges, fragmented workflows, productivity drains, and increasing reliance on contract research organizations (CROs) among them. How can organizations overcome these challenges to reap the benefits of a small molecule drug discovery renaissance?

Keys to Success in Small Molecule Drug Discovery

Success in the small molecule drug discovery renaissance will hinge upon multiple variables:

Data Management

We must keep pace with advances in computational design by also investing in next-generation lab-data management technology that lets us efficiently merge, manage, and use all data, no matter where they were derived.

Research Collaboration

We must support novel cross-discipline research paradigms that help scientists move beyond the traditional scope of small molecule discovery to better understand targets.

Workflow Optimization

We must optimize small molecule drug discovery workflows—from hit identification to lead optimization to candidate selection—in order to meet increasing demands to improve cycle times, reduce costs, and find better candidates, faster.

Let's look at each of these variables at length.

Data Management in Small Molecule Drug Discovery

The ubiquity of cloud computing means it's no longer just the biggest players with access to the computational resources needed to undertake massive-scale virtual exploration. Even the smallest start-ups can virtually screen millions of compounds to uncover hits or perform lead optimization analyses once deemed out-of-reach due to their intense computational demands.

But when do we transition from the *in silico* (or web lab) world back to the wet lab? Sooner, rather than later, many experts suggest. By testing and developing virtual leads in the web lab, researchers can learn more about them and help inform subsequent phases of discovery and development.

In order to make this transition as seamless as possible, teams need to be outfitted with technology infrastructure that can efficiently handle the volume and variety of data flowing out

of computational exploration and merge it with the scores of data coming from lab exploration, whether that be structural data, assay results, toxicology assessments, etc.

By some estimates, researchers can spend up to 42% of their time [on administrative tasks](#), rather than on actual research. Freeing just a fraction of this time can pay off in dividends. When teams have easy access to a united source of trustworthy data, they gain better insight into the big picture and researchers can optimize time at the bench, instead of wasting time manually searching and exchanging data, repeating experiments, or following dead leads.

Research Collaboration in Small Molecule Drug Discovery

Collaboration will also play a key role in extending the scope of traditional small molecule research paradigms.

Beyond investing in the latest and greatest technologies to enable scientific exploration, organizations must also facilitate teamwork amongst research groups whose members have historically worked in relative isolation, with different workflows, tools, and data types.

For example, to improve target understanding, proteomics teams exploring new or poorly understood protein pockets on well-validated targets must be given tools to collaborate and share data with chemistry teams searching for novel compounds that selectively interact with those pockets. If any of those team members are from outside CROs, security also becomes a key concern.

The best way to facilitate this type of collaborative, boundary-breaking research is with an end-to-end research informatics platform that enables organizations to:

- Unite proteomics and chemistry teams (along with all their tools and data) on a single platform that not only improves collaboration, but also reduces technical debt and total cost of ownership.
- Have one place to manage everything—design, synthesis, sample logistics, quality control analysis, screening, and SAR analysis.
- Get up-and-running quickly and seamlessly scale as projects, data, and teams grow.
- Collaborate with CRO partners using secure cloud data exchange.

Workflow Optimization in Small Molecule Drug Discovery

Industry [estimates](#) indicate that there has been a 12% increase in research and development costs in recent years. The burden of offsetting these increases tends to trickle down, leaving small molecule discovery teams with no other choice but to optimize their processes.

Undoubtedly, optimization in early discovery can reduce the cost of downstream failures in clinical testing, trials, regulatory review, and commercialization. However, with small molecule drug discovery workflows becoming increasingly complex and data volumes skyrocketing, it is not an easy task to get everything and everyone working together toward a common goal of finding better candidates, faster.



Haydn Boehm, PhD, is Director of Product Marketing at [Dotmatics](#), a provider of research and development services with scientific software connecting science, data, and decision-making based in the United Kingdom.

OPINION

“Cancer Moonshot” Represents a Call to Arms for Clinical Trial Practitioners

David J. Morin, MD, FACP, CPI, FACRP, 2022 Chair of the Association Board of Trustees for ACRP



On September 12, 2022, the White House announced the National Cancer Institute’s Vanguard Study on Multi-Cancer Detection to assess the potential of biomarkers for early cancer detection and prevention. This is one component of the “[Cancer Moonshot](#)” launched in 2016 with an ambitious goal of marshalling federal resources to significantly reduce cancer deaths in the next several decades.

When we look at healthcare strategies, we have two broad options. We can prevent disease, or we can treat it. Obviously, prevention is preferable, but requires an understanding of causation. Sometimes the cause is environmental—such as that between smoking and lung cancer. It may be biological, as seen with higher rates of diabetes in obese patients. It may be genetic, as with breast and colon cancer. Or it may be a combination of factors.

However, we still do not understand what causes many cancers and this announcement, coming on the 60th anniversary of President Kennedy’s Moonshot Address about the goal of landing humans on the moon and returning them safely to Earth, comes at a time when our understanding of genetic markers provides many potential tools to pre-identify those at risk.

The majority of cancers do not have known screening markers, and this research is needed to be sure potential biomarkers are predictive of disease, reduce mortality, do not lead to unnecessary procedures or needless worry, and are cost-effective. This will require intense study and a long-term commitment, not unlike the original Moonshot announcement. I remember watching with intense interest and fascination in the 1960s the many successes of NASA—and occasional painful failures—that eventually led to multiple successful moon landings.

One question raised in the midst of social upheaval in the 1960s was whether that money for the so-called Space Race could have been better spent on programs to help the poor. Today, it is widely recognized how the technological advancements NASA accomplished led to many products, processes, and breakthroughs that we may take for granted, but which have undoubtedly improved the quality of life for many. The Vanguard Study is the next step in a process that has the potential to directly benefit us and future generations. The focus this time is on human research with a direct potential benefit to humankind. ACRP's mission is to support excellence in clinical research worldwide as clinical trial practitioners are a key to these efforts, along with the valued contributions of study participants.

As a practicing physician, researcher, husband, and father, there is no diagnosis wrought with more anxiety and fear than a diagnosis of cancer. It will take many years to assess the potential benefits of these technologies, but now is the time to take these bold steps.



In addition to his volunteer duties with ACRP, Morin provides patient care and serves as the Director of Research at Holston Medical Group, a multispecialty practice in Tennessee and Virginia, and is Director of the High-Risk Disease Prevention program for a Fortune 100 company.

ON THE JOB

Lessons from Female Innovators in Clinical Research

Elizabeth Weeks-Rowe, LVN, CCRA



Innovation is the strongest voice in the developmental narrative of clinical research. It drives adaptive study design, advanced data collection/reporting, and alternative research methods to ensure business continuity in times of crisis.

Innovative technologies have transformed the landscape of clinical research forever, including through revolutionized data collection practices with the advent of systems for electronic data capture

(EDC), electronic patient-reported outcome (ePRO) measurements, and electronic source/regulatory capabilities.

Early EDC systems helped reduce the need for paper case report forms and associated data collection measures that were slower, less efficient, and less accurate. Those early systems, self-contained and archaic by today's standards (anyone remember lugging the extra EDC laptop to monitoring visits?), still revolutionized data efficiency and accelerated data transmission. EDC systems have since evolved to web-based/cloud-based technology that incorporates automated review to track data discrepancies, issues, and questionable reporting trends at the site/patient level and across trial centers. These systems can be accessed by many users at any place with a secure internet connection.

ePRO technology helped facilitate early patient centricity initiatives by providing patients more accessible and streamlined tools for personal reporting of trial endpoint data (e.g., eDiaries, pain reports, and quality of life questionnaires) and embedding their voices in early trial outcomes.

Innovative regulatory portals accelerated regulatory start up and submission timelines to meet the critical need for effective vaccines during the pandemic. Meanwhile, innovative platforms (e.g., Zoom, Microsoft teams) transformed an antiquated monitoring process into a more accessible, transparent, and accurate methodology (remote/virtual monitoring) that enables real-time data access, review, and site/contract research organization (CRO) communications.

A New Era for Innovation

Innovation has heralded a new era in which talent, work ethic, and transferable skills are the differentiating factors in job consideration. Diversity—both in terms of ideas and background—is truly valued as an element of one’s contributions to an organization, as opposed to being a rote consideration that is often dismissed as being necessary to satisfy a quota.

Innovation is wrought by visionaries—trail blazers with the alacrity/vision to anticipate potential crises and successfully and quickly adapt to forestall them, as opposed to accepting chaos as the forced catalyst for change. Some of these visionaries are gifted women who may have once been underestimated and unrecognized for their talents.

Featured here are insights from women in clinical research who have used creativity and ingenuity to forge passageways through a once-impenetrable career ceiling by crafting alternative curriculum and training delivery for broader access during the pandemic, or blazing a path over barriers to site ownership, or fueling their ambitions across a career trajectory from clinical research associate to CRO director in less than 10 years. All of them have challenged the status quo and had a remarkable impact on the clinical research enterprise.



Lauren Ballina Chang, MS, CCRP

In her role as vice president of strategic growth with Clinical Research Fastrack’s boot camp-style of training organization for new clinical researchers, Chang has an inspirational career story involving an innovative pathway to leadership. She explained that “as an educator, mentor, innovator, entrepreneur, and clinical research professional, creativity has been the most unexpected asset in my skillset arsenal.”

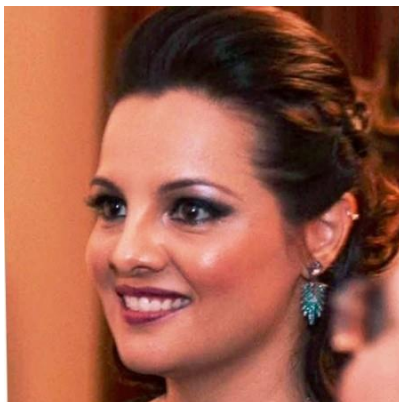
Chang started and grew her career at the site level running primarily investigator-initiated trials. She had an early introduction to the constant problem-solving/pivoting that made the job engaging, rewarding, and interesting. Though she loved working at the site level and being patient-facing, she truly found her passion helping others start their careers in clinical research.

Now part of the leadership team at Clinical Research Fastrack, she is always evaluating the research field for trends and finding new ways to help aspiring clinical research professionals seeking training. She describes the incredible shift forced by the pandemic to ensure business continuity: “Until COVID hit, all our trainings had been delivered in person in a physical classroom setting. As the world shut down, there was a moment of panic—was this [the end] for our training organization?”

Describing how the company’s team responded with the innovation and creativity required to ensure it could continue to deliver critical content to its students, Chang noted how, “Once again, it came down to creativity as well as an incredible team. We transformed our curriculum in four days to be delivered entirely via video conference. The challenges: make it engaging, make it interactive, give our students the skills they need to have a successful career, and cultivate a feeling of hope.”

The pivot had transformative results; the company has reached a larger audience with the convenience of the video conferencing platform, and those from less privileged backgrounds can participate due to decreased barriers to attend virtually vs. in person. Trainees can also now engage with more instructors from all over the country rather than just those who could come into the classroom.

The company’s rapid adaptation to a major challenge became its new paradigm for more accessible learning. Chang is proud of how that collaborative effort, resulting from creative problem-solving, extended the reach of Clinical Research Fastrack and amplified its ability to transform the research industry.



Roberta Perrella, BS Pharm

Perrella is a pharmacist by education and currently an associate director of clinical operations with a major science company. For her, the pathway to leadership was a process of fully understanding the passions that would drive her career choices. She ultimately decided to attend pharmacy school, and with her dedication to science and advancing drug development, a career in clinical research was the logical next step. By now, she has worked for almost 20 years in the clinical research field, starting as a clinical research associate (CRA) in Brazil, and then working her way up to CRA manager roles, managing teams and having oversight responsibilities over site start-up deliverables in several Latin American countries.

Attributing a portion of her success to “out of the box” career choices, she notes how, “Before joining my current company, I took a quick break from research and accepted a job with a big pharma company. They hired me to lead one of their marketing projects on growth hormone disorders in children. I was interested because not only [did it have] a science component, but it was also an opportunity to expand my knowledge on the pharma sales business.”

Perrella says she received the best career advice ever from her manager at the time. “She advised me that in order to be successful and sustain that level overtime, I should not rush things out. Rather, I should take one steady step at a time, build a solid foundation, and it will do wonders.” She applied this advice to her career and attributes her developmental trajectory to doing so. This is also the philosophy she conveys to whatever team she is managing.

Her ability to embrace new opportunities led her to relocate to the U.S. to work as a CRA manager in study start-up, and it’s a decision for which she says she has no regrets, noting that she has enjoyed assimilating a new culture—both personally and professionally. The foundation for a successful clinical research career journey, according to Perrella, is “getting involved with and embracing organization changes and opportunities to collaborate cross-functionally across the globe.” She describes being inspired by the leaders, direct reports, and colleagues who crossed her path; those experiences motivate her to continue to do her best every day.



Susan, the Site Owner

Susan was a site owner with whom I worked on a diabetes trial. She was the director of three research sites with a fourth one opening in the next quarter. We first met at a site evaluation visit, where I soon learned her remarkable clinical research success story. She had worked in clinical research for 15 years, starting as a study coordinator at a dedicated research site.

After several years in her first job, Susan became frustrated with her inability to affect change and correct deficiencies in the trial and personnel management process. She had an epiphany; the only way she could fully implement and control a successful trial enterprise was to open a clinical research site. She partnered with several former investigators, acquired the necessary funding, erected a solid site infrastructure with policy and process based on her and the investigators expensive experience, and opened a dedicated clinical research site focused on diabetes study conduct.

Another successful site opening followed, and eventually she was part owner and director of research for three dedicated clinical research sites. She proudly informed me that her daughter had entered the clinical research field after college graduation and was preparing to manage the organization's fourth clinical research site, set to open in several months. She decided early on that she would blaze her own path, and knock down any barriers blocking her progress, whether financial or situational in nature, or due to ridiculous bias.

Conclusion

Female innovators are the driving force for positive change to the clinical trials landscape, and we continually benefit from their creative vision for staff empowerment, research integrity, and passion that drives clinical trial improvement.

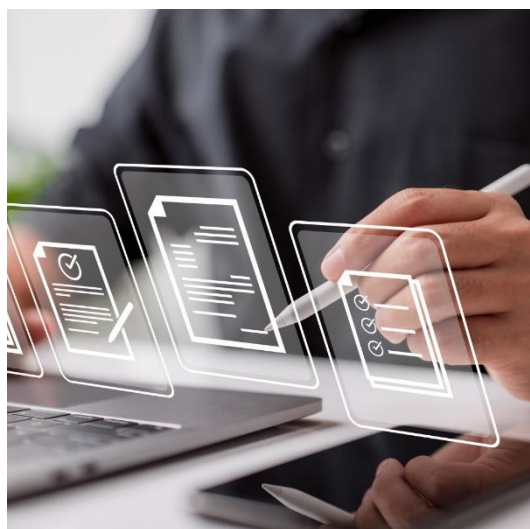


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DATA-TECH CONNECT

**Electronic Lab Notebook Adoption in Clinical Research:
5 Strategies for Success**

Vega Shah, PhD



Electronic laboratory notebooks (ELNs), when used in clinical research labs, can allow for increased efficiency in recording experimental results, help maintain data provenance, and provide greater reproducibility. An ELN can also allow principal investigators (PIs) to oversee lab research and manage documentation in a structured way to meet regulatory requirements. Further, the ability to integrate ELNs containing preclinical data to patient information stored in electronic medical records or electronic

health records can be a boon for clinical data managers seeking to improve traceability.

In addition to the specific benefits listed above, the use of ELNs for clinical and preclinical lab research can provide several other benefits. For example, adherence to the [FAIR data principles](#) recognized by the [National Institutes of Health's Office of Data Science Strategy](#) can make academic labs favorable candidates to receive federal funding.

Broadly, digital records stored on a web-based ELN can allow PIs and lab managers to prevent loss of information due to employee turnover, accidental damage to physical devices like laptops, or illegible handwritten laboratory records. All these measures can generally make experimental results easier to find and share.

Cautionary Notes

However, the transition from paper notebooks to ELNs is not without challenges. The current market for life sciences software consists of a vast variety of products that can assist lab researchers in documenting experiments, workflows, and protocols while allowing for collaboration. The process of choosing the right ELN is a difficult one, and must account for budget, ease of use, scalability, and whether the software of choice will continue to be supported for the foreseeable future.

Even after accounting for the above needs, an important yet hard to define issue lies ahead—user adoptability. Organizations face loss of time and resources when their users are unable to adopt ELNs successfully.

A Real-World Scenario

A 2022 study published in the [*Journal of the Medical Library Association*](#) presents a case study for implementing an institution-wide ELN for more than 800 lab employees at the Indiana University School of Medicine. The study consists of two stages—an initial pilot with a small subset of users (67) that was followed by a survey to record reasons for successful adoption, then full implementation spanning a one-year period and expansion to 829 users.

This case study is especially impactful due to the sheer number of scientists who were able to successfully adapt to the use of ELNs. The study summarizes the main strategies to encourage cultural and behavioral change in lab employees that can result in successful ELN implementation. The authors found that there were five key drivers of change:

- **Infrastructure**—Centralizing licensing and easy access to ELN accounts for all lab scientists on a cloud-based platform.
- **User Interface and User Experience**—Lab scientists reported that their work became easier and more efficient after switching to an ELN, specifically through the use of experimental templates, shared protocols with their team, standard naming conventions, and widgets for routine analysis/calculations.

- **Communities**—Establishing resources and avenues that allow users to share knowledge can help create safe spaces to learn. Popular mediums include wikis, office hours, or dedicated groups on chat-based apps like Teams or Slacks.
- **Incentives**—In this study, users were mainly incentivized via added efficiency to their work and the ability to use handheld devices like mobile phones and tablets in their laboratory workflow. However, there are other strategies smaller organizations can employ; for example, an established weekly social hour for lab workers to collectively update and share ELNs.
- **Policy**—In order to change research culture and behavior, an organization's policies must directly address ELNs. In addition, the policies should clearly describe how ELNs should be used and their net benefit to the organization.

Conclusion

The process of replacing an age-old practice—hand-filled paper notebooks—with ELNs remains not just a technical challenge, but also a social one. Successful adoption is intertwined with the people and culture of science. To successfully implement ELNs and other laboratory information management systems, organizations must focus not just on the technical side of handling data, but also the key catalysts of behavioral changes in scientists conducting preclinical and clinical bench science.



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OVER THE TRANSOM

What's Keeping You Up at Night?

Edited by Gary W. Cramer



Years ago, I (mostly in jest) tried to convince a former Editor-in-Chief for ACRP that we should take advantage of having an October issue of *Clinical Researcher* by putting pumpkins on the cover and calling it our Fall Harvest Special, or something of that nature. She failed to appreciate my initiative. However, the urge to tie the theme for an issue into spooky season has never dimmed in my heart and now, at last, I have a decent excuse to get it out of my system.

As I write this during and in honor of Michael Causey's last week as Editor-in-Chief for the Association, I wish to further a fact-finding mission he recently launched in the ACRP Community to learn about "[What's Keeping You Up at Night Professionally?](#)" Please feel free to contact me directly at gcramer@acrpnet.org with your feedback on this topic so that Michael can enjoy his return to the world of freelancing after seven years in the clinical research trenches.

In the meantime, here are excerpts of missives from organizations outside ACRP about how they are tackling some of the thorniest "monster in the closet" challenges keeping their leaders, staff, and stakeholders up at night (no endorsements implied).

Diversity Worries and Woes

U.S. Food and Drug Administration (FDA)-approved clinical trials have historically lacked diversity among participants who are largely white adults (mostly males) from affluent socioeconomic backgrounds, and in trials that are often based in majority-white regions of the world. Meanwhile, the Indian subcontinent is home to about a quarter of the world's population, yet less than 2% of global clinical trials have any study sites in India. Moreover, clinical trial participants do not reflect the racial and ethnic makeup of the global population affected by various targeted diseases. This lack of diversity in patient clinical trials is counter-productive to research goals, particularly in studies involving ultra-rare diseases where a small number of affected patients are sparsely distributed geographically within the U.S. and globally.

The U.S. biopharmaceutical industry struggles to enroll the required number of patients in orphan drug clinical trials within the U.S., requiring a more global enrollment strategy. From the perspective of rare diseases patients located in countries without local access to clinical trials, they remain unable to access novel treatment options. Neither science nor patients are well served, causing an increased burden on the orphan drug development process.

“The current process for developing new treatments for rare diseases leaves India and the Indian diaspora on the outside looking in,” [says](#) Harsha Rajasimha, PhD, founder and executive chairman of the Indo-US Organization for Rare Diseases ([IndoUSrare](#)). “Indian patients miss out on opportunities to avail clinical research as a care option or join a clinical trial that offer the best hope for timely care management. Then when drugs are eventually approved, they are based on safety and efficacy data from mostly non-Indian patients.”

In 2021, the Indian government revived the National Policy for Rare Diseases to assist people with rare diseases. Eight centers of excellence for rare diseases recognized by the policy are working with patients and medical geneticists to identify individuals needing this help.

To Decentralize or Not?

Velocity Clinical Research, an integrated research site organization, has [announced](#) the findings of a U.S. patient survey aimed at better understanding patient preference for study

decentralization activities in clinical research. Conducted in the first half of 2022, the survey gathered 1,129 responses. Questions focused on study design and decentralization methods, in order to understand people's previous experience with trials and preferences for future participation. The major findings include:

- Patient-facing technology is not widely used in research today and most patient experience of technology is of relatively simple modalities such as eDiaries. However, volunteers of all ages are overwhelmingly willing to use it.
- Home visits will not solve racial and ethnic diversity issues, and could exacerbate them.
- Sixty percent of volunteers ages 18 to 34 have participated in multiple studies.

Velocity says the research shows that people like the flexibility of decentralized methods and a hybrid model of in-person and virtual study visits, with in-person visits taking place at the clinic rather than at home. According to the company, the findings have implications on protocol design, patient recruitment techniques, and technology development, which should all be focused on reducing patient burden. You can access a presentation on the report [here](#).

Putting Your Data to Work

STAT, a media company reporting on health, science, and medicine, has partnered with Applied XL, a company that builds real-time information systems rooted in computational journalism principles, to release a new platform called [STAT Trials Pulse](#), which allows for early detection of potential outcomes in clinical trials data.

In the last 12 months, more than 2.5 million changes were recorded in the U.S. clinical trials registry alone. That's an average of more than 6,800 updates every day. Trying to analyze these changes, identify patterns, and connect the dots between other sources is a staggering undertaking, but is also essential for investment firms and pharmaceutical companies seeking competitive intelligence. From the enormous stream of data, Applied XL's algorithms detect important clinical trials updates, add context against historical data, and fill in the blanks with additional data sources to deliver a curated drip of what the partners call "actionable alerts."

STAT Trials Pulse has been in beta since January 2022.

Making Room for Inclusivity

To stay ahead of the urgent needs of equitable healthcare, Martis Capital, a middle market healthcare fund, has [announced](#) its investment in Alcanza Clinical Research. Founded in December 2021 and named for the Spanish word “reach,” Alcanza is a clinical research site network platform dedicated to creating a sustainable and inclusive clinical trial environment for all.

As patient advocacy groups, research stakeholders, and regulators urge sponsors to expand clinical trial inclusion, Alcanza is actively transforming the model for research access to underrepresented populations across different races, ethnicities, genders, sexual orientations, disability statuses, and more while enhancing clinical research quality and patient recruitment efforts. As a first step, Alcanza has acquired five high-performing clinical research companies. These include Coastal Carolina Research Center, Boston Clinical Trials, ActivMed and Allcutis Research, Quest Research Institute, and Charlottesville Medical Research across eight locations in Massachusetts, Michigan, New Hampshire, South Carolina, and Virginia.

“This partnership is a unique opportunity to drive sustainable improvements in the highly fragmented clinical trial space by focusing on improving disparities in clinical research,” said Mario E. Moreno, managing partner at Martis Capital.



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