# Clinical Researcher
# October 2022
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**Clinical Researcher—October 2022 (Volume 36, Issue 5)**

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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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 templatize 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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PRESCRIPTIONS FOR BUSINESS

# 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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**ACRP HOME STUDY**
**CLINICAL RESEARCHER—OCTOBER 2022 (VOLUME 36, ISSUE 5)**
*What's Keeping You Up at Night?*

## Article #1: **Diversity, Equity, and Inclusion in Patient Recruitment and Retention**

LEARNING OBJECTIVES
After reading this article, the participant should be able to summarize the importance and current status of diversity, equity, and inclusion (DEI) among clinical trial patients, and to outline multiple suggested solutions for addressing DEI-related issues.

DISCLOSURES
Kate Schroeder; Seth Palmer, MBA, CDMP: *Nothing to disclose*

**1. According to a recent U.S. Food and Drug Administration report and U.S. Census data, by how much does participation in clinical trials by people of color fall short of their representation in the U.S. population?**
a. Less than 5 percentage points.
b. Between 7 and 9 percentage points.
c. About 12 percentage points.
d. More than 15 percentage points.

**2. The article notes which of the following conditions as disproportionately affecting Asian Americans and Pacific Islanders?**
a. Prostate cancer
b. Colorectal cancer
c. Cervical cancer
d. Gastric cancer

**3. A recent survey found more than 30% each of transgender and nonbinary respondents reported having avoided medical treatment for which reason?**
a. Low income
b. Fear of discrimination
c. Legal barriers
d. Transportation issues

**4. Financial incentives for participating in clinical trials rarely outweigh which of the following related costs for people of lower socioeconomic status?**
a. Transportation, lodging, and time away from work.
b. Trial medications, equipment, and insurance needs.
c. Inclusion/exclusion tests, sample handling, and follow-up.
d. Informed consent, randomization, and monitoring.

**5. The authors suggest which of the following to address the lack of diversity and inclusivity in clinical research?**

a. Recruiting more patients into non-U.S.-based multinational trials.
b. Doubling the financial incentives for patients to join clinical trials.
c. Improving diversity and inclusivity among healthcare professionals.
d. Federal mandates for specific levels of racial representation in trials.

**6. An Association of American Medical Colleges survey found nearly 9% of medical students graduating in 2019 identified with which community?**

a. Asian American/Pacific Islander
b. International
c. LGBTQIA
d. Non-Christian

**7. The authors suggest which of the following steps toward destigmatizing clinical research?**

a. Establishing an independent watchdog organization on federally funded trials.
b. Listing and thanking all participants of clinical studies in a public database.
c. Featuring celebrity endorsements of their participation in successful trials.
d. Building trust through the messaging and recruiting around clinical trials.

**8. Patient respondents to one survey indicated they would appreciate and use a platform to do which of the following related to clinical trials?**

a. Report suspected conflicts of interest on the parts of principal investigators.
b. Provide anonymous feedback for their healthcare professionals.
c. Encourage others with their medical condition to join ongoing studies.
d. Be hired to help sponsors design better protocols for the next phase of trials.

**9. The ease of travel to and availability of parking at a study site's location are considerations for increasing which of the following for potential participants?**

a. Accessibility
b. Compliance
c. Compensation
d. Survival

**10. The authors suggest having more researchers at study sites capable of which of the following?**

a. Recruiting patients with rare diseases.
b. Covering multiple therapeutic areas.
c. Participating in trials themselves.
d. Speaking multiple languages.

*[Home Study continues on next page…]*

## Article #2: **With a Reinvigorated Focus on Vaccine Research, Why Are We Still Using Dated Approaches?**

LEARNING OBJECTIVES

After reading this article, the participant should be able to describe a variety of trends, tactics, and challenges in the application of decentralized clinical trial technologies to vaccine studies.

DISCLOSURE

Musaddiq Khan, MBA: *Nothing to disclose*

**11. Clinical trials for vaccines have been slow to take up which of the following elements of study design?**

a. Observation
b. Parallel study
c. Randomization
d. Decentralization

**12. Why are manufacturers less incentivized to develop vaccines than ongoing treatments?**

a. Shorter windows for patent exclusivity.
b. Lower profit-making opportunities.
c. Higher risk of product failure/lawsuits.
d. Falling demand for new infectious diseases.

**13. Why do U.S. public policymakers support vaccine development efforts?**

a. To better keep pace with international biopharmaceutical industry trends.
b. To foster new employment opportunities in underdeveloped rural areas.
c. To see returns on investment in healthcare savings, wages, and productivity.
d. To appease lawmakers facing public demand for new and improved treatments.

**14. Which of the following is noted by one source for this article as a reason organizations may resist decentralization of vaccine trials?**

a. Concern that so many potential investigators have refused to take on such studies.
b. Worries that levels of offsite adherence to the protocol are almost nil for vaccines.
c. Fear that any additional layers of complexity could result in enrollment delays.
d. Threats of legal action from patient advocacy organizations over decentralization.

**15. A Tufts Center for the Study of Drug Development study touts which of the following as benefits of decentralized clinical trials (DCTs)?**

a. Lower screen failure rates and fewer protocol amendments.
b. Decreased investigator oversight and sponsor expectations.
c. Fewer patients needed for Phase II and III decentralized trials.
d. No need for FDA Investigational New Drug applications for such trials.

**16. Which of the following characteristics are among those that make vaccine trials ripe for templatization?**

a. Their applicability to rare diseases.
b. Their conduct over many years.
c. Their low volume of participants.
d. Their relative homogeneity.

**17. Which of the following is a source of difficulty in managing the logistics of vaccine trials?**

a. A Phase III efficacy trial may have nearly 40,000 participants.
b. Volunteers tend to be clustered in remote or impoverished areas.
c. Most participants will only sign on under conditions of total secrecy.
d. Many study sites are never offered opportunities for such trials.

**18. Which of the following is said to be an advantage of decentralization in vaccine trials?**

a. It can decrease the necessity of institutional review board involvement.
b. It helps to expand geographic access for greater population representation.
c. It makes regulatory authorities more likely to approve postmarketing studies.
d. It encourages sponsors to test a vaccine against multiple disease targets.

**19. By how much can a pre-packaged vaccine DCT-in-a-box reduce study startup time?**

a. Less than 10%
b. About 25%
c. No more than 35%
d. At least 50%

**20. A standardized DCT platform should facilitate which of the following to build trust between participants and site staff?**

a. One-on-one communication
b. Rapid compensation
c. Minimal protocol amendments
d. Decreased adverse events

*[Home Study continues on next page…]*

## Article #3: **The Business Case for Patient Experience**

LEARNING OBJECTIVES

After reading this article, the participant should be able to discuss the benefits to the conduct of clinical trials, return on investment, and data quality that may be realized from investments by and mindfulness among sponsors and sites regarding patient experience.

DISCLOSURE

Scott Gray: *Nothing to disclose*

**21. According to the article, what is a typical patient dropout rate during a clinical trial?**

a. Less than 10%
b. Roughly 25%
c. More than 30%
d. Nearly 50%

**22. How many clinical trials are said to finish on time?**

a. 6%
b. 12%
c. 18%
d. 24%

**23. According to data published in 2018, what is the median cost of clinical trials for a new drug seeking approval from the U.S. Food and Drug Administration (FDA)?**

a. $7 million
b. $19 million
c. $36 million
d. $55 million

**24. Phase III trials for new drugs approved by the FDA are said to cost how much?**

a. Less than half as much as a Phase II trial.
b. About the same, regardless the country involved.
c. More than twice as much as just five years earlier.
d. A median of more than $41,000 per patient.

**25. What effect can the rarity of a disease have on patient participation in trials for treatment of it?**

a. Sponsors may refuse to pay patients for travel of more than 50 miles to reach a trial site.
b. All patients with a particular condition are likely to be found in a single, urban region.
c. Patients may be scattered geographically in clusters and face travel burdens to sites.
d. New study sites will often be established as close to the most promising patients as possible.

**26. The author characterizes which of the following as being “pivotal to completing clinical trials”?**

a. Study protocol
b. Patient experience
c. Investigator oversight
d. Site initiation

**27. Which of the following are listed as being benefits from investments in patient experience programs for sponsors?**

a. Obtaining better data and decreasing the likelihood of trail deviations.
b. Directing less compensation to sites for future enrollment efforts.
c. Needing fewer participants to complete the average Phase III study.
d. Finding multiple therapeutic targets for the same drug treatment.

**28. Drugs developed with patient-centric processes have been reported as how much more likely to launch than those produced without them?**

a. 5%
b. 20%
c. 35%
d. 50%

**29. An independent study found that almost all clinical trial patients have seriously considered dropping out of a study for which of the following highlighted reasons?**

a. Adverse events
b. Dislike of the investigator
c. Placebo effect
d. Travel-related challenges

**30. Every respondent to the same independent study noted the importance of which of the following?**

a. Ensuring they could stop and restart their trial participation at any time.
b. Learning the results of the trial before they were published.
c. Having a dedicated person to help them manage trial logistics.
d. Being compensated for recommending joining the trial to other patients.