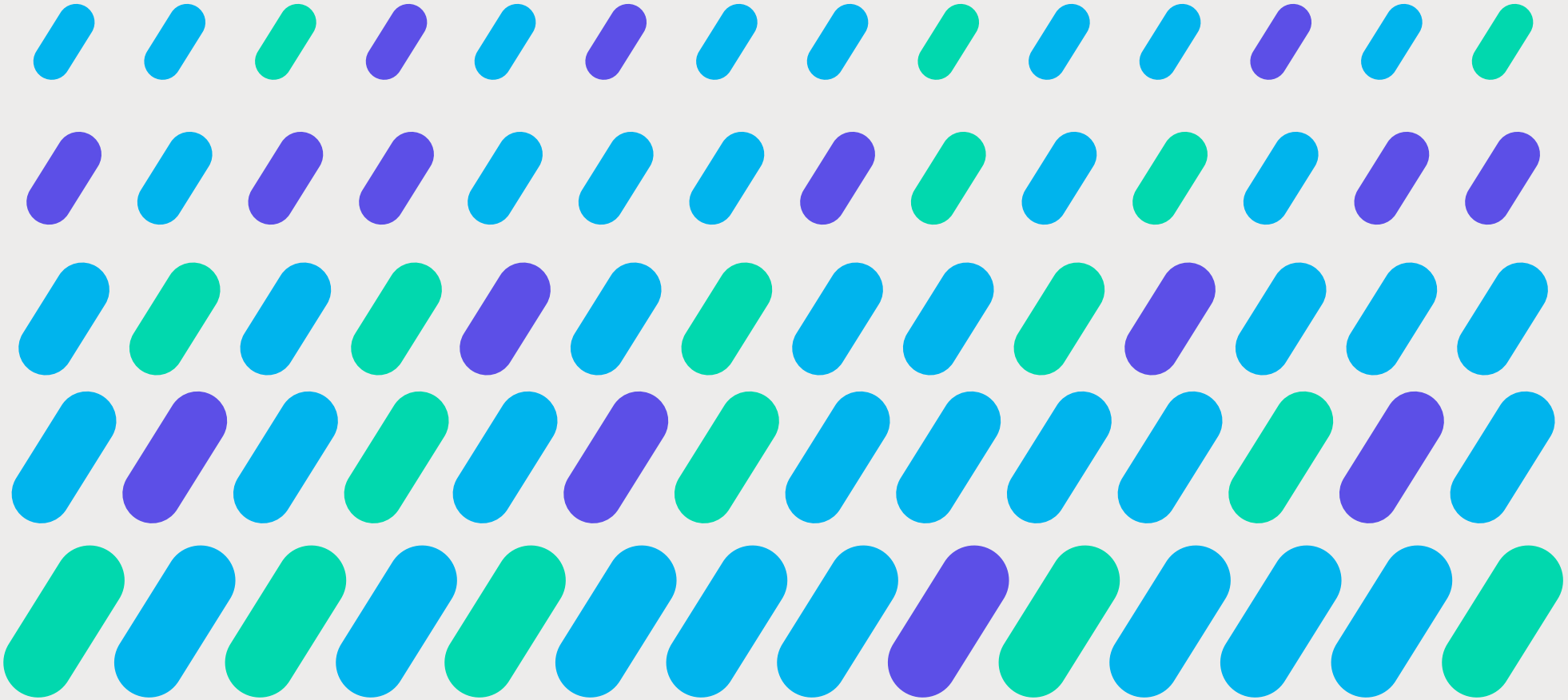
HOW SPONSORS CAN ACCELERATE STUDIES BY CAPITALIZING ON CLINICAL TRIAL AWARENESS TRENDS

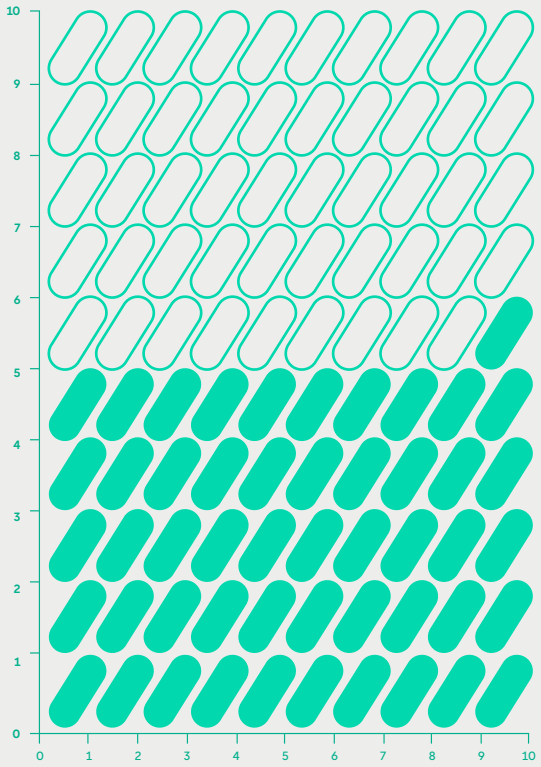
What's Next For Clinical Trial Recruitment and Engagement?



Finding patients willing to volunteer in clinical trials has been a persistent problem for sponsors. When you add increasing study complexity and demands on volunteers, keeping those individuals engaged is an equally critical need. Most trials don't enroll on time, and sponsors do not have the information to effectively apply additional resources across their studies to improve recruitment and retention.

Since March 2020 and the new generation of pandemic-era consumerism, public attention around clinical trials has been on the rise. This can be positive and negative. The positive is that many have now seen firsthand what medical research can achieve. The negative is that the notion of clinical studies has again become politicized beyond the science.

Regardless of the position taken on the topic, awareness and interest surrounding clinical trials are shifting. In this playbook, industry experts share their unique perspectives on those evolving behaviors and what they mean for biopharma sponsors.



51% said they would be willing to take part in a study

An Evolving Landscape for Clinical Research

But awareness — even when it's positive — is just half the equation, said Tyler Bye, Director, Program Strategy and Product Development at WCG. "Many people have said that if they were approached for a clinical trial, they'd join — but you hear so often about people not even being approached," Bye said. "With the recent vaccine studies, the opportunity was put in front of everyone to join. What it showed isn't so much that people weren't aware previously, but rather that they'd never been given the opportunity."

What gives certain trials such as vaccine studies an advantage isn't just that the moral imperative is on the world's stage, but also something much simpler: access. Access is particularly important for diversity, equity and inclusion in clinical trials, which has been the subject of recent Food and Drug Administration guidance and even national legislation.[2] Researchers have tracked increasing awareness among underrepresented populations in research,[3] which emphasizes the need for sponsors to capitalize on those trends with a broader focus on accessibility, experts say.

1. https://www.wcgclinical.com/insights/public-awareness-of-clinical-research-and-the-path-to-diversity-in-clinical-trials/

2. https://news.bloomberglaw.com/pharma-and-life-sciences/diversity-in-clinical-trials-at-fda-gets-a-boost-from-new-law

3. https://www.appliedclinicaltrialsonline.com/view/awareness-of-clinical-research-increases-among-underrepresented-groups

Digital health has helped increase participation by making protocols more accessible to more people through tools that electronically enroll participants. Now, patients may have access to decentralized trials or hybrid trials, instead of only traditional-site based studies.

Despite the momentum from digital health and other R&D developments, there have been some setbacks in the clinical research universe. Among them is the fact that trials still have lingering skeptics. Amy Thue, Associate Director, Project Management at WCG, suggested that the trend coincides with the optics of having products hit the market faster than previously possible.

"Heightened awareness of clinical trials has also brought an additional level of scrutiny — especially when experts have been all saying new products usually take five or more years to get to market," Thue said. "There has been a misunderstanding that there can be a safety issue when products develop faster. What is needed is more public education to restore trust in research."

More than anything, this intersection of trends means sponsors should think more intentionally about recruitment and retention moving forward, she added. With the right strategy, sponsors can take advantage of the shifting awareness, narrow knowledge gaps, and finally (hopefully) address concerns with sluggish enrollment that have plagued the industry for years.

"There has been a misunderstanding that there can be a safety issue when products develop faster. What is needed is more public education to restore trust in research."

—AMY THUE, ASSOCIATE DIRECTOR, PROJECT MANAGEMENT, WCG

Rethinking Recruitment and Retention for a Changed World

Despite their outsized influence on trial success, recruitment and retention—particularly around data entry—have historically been underestimated with respect to the time and attention required. When any one aspect is underprioritized, it can create a cascading impact on study timelines.

So, given that finding and keeping patients are, in fact, linchpins of a successful trial, how can sponsors give these steps the attention they need considering recent swings in public awareness? Here's what Bye and Thue recommend:

1

UNDERSTAND PATIENT MOTIVATIONS

The phrase "patient centricity" has become popular over the years as sponsors shape their protocols to better meet patients' unique needs. But even with all the time, resources and money spent on making studies more patient-centric, some sponsors still misunderstand a central component of the patient experience - their motivation.

"A lot of times, sponsors think that people join research to better humanity," Thue said. "While that's a reason, sponsors should consider that what motivates patients—particularly anyone who's not a healthy volunteer—is finding a treatment for their disease. With the reduced number of investigators who participate in clinical research and the increased complexities of clinical research trials, we need to bring it back to the patient in what motivates them."

Clinics and hospitals participating as study sites, by and large, do this exceptionally well. But with ongoing resignations and burnout facing healthcare, many sites are increasingly underresourced to manage the critical human interactions and build patient trust as they would like. Thue said this marked an important opportunity to support sites by understanding the support capacity they might need, which may include dedicated clinical research coordinators.

"Resourcing is incredibly important at the site level to maintain that extra layer of comfort through the informed-consent process and beyond," she said. "We need to ensure that there's a resource to stay focused on that trial's patients and restoring trust in the system with compassion and education."

"We need to ensure that there's a resource to stay focused on that trial's patients and restoring trust in the system with compassion and education."

—AMY THUE, ASSOCIATE DIRECTOR, PROJECT MANAGEMENT, WCG

2

EDUCATE AND EMPOWER

If the politicization and misinformation of medical research continue to be a reality, then sponsors should serve the important role of educator, Bye added. Filling knowledge gaps or correcting misperceptions can help affirm the importance of clinical trials while supporting recruitment and retention.

"We need more people evangelizing the good parts of research — the reasons to join a study, what it means for patients and what it means for populations," he said, adding that Pfizer's "thank you" campaign video[4] served as a shining example of just that. "There's a lot that the industry at large can do to keep the good news and the momentum out there so that the politicized voices aren't the loudest ones."

"We need more people evangelizing the good parts of research — the reasons to join a study, what it means for patients and what it means for populations. There's a lot that the industry at large can do to keep the good news and the momentum out there so that the politicized voices aren't the loudest ones."

—TYLER BYE, DIRECTOR OF PROGRAM STRATEGY AND PRODUCT DEVELOPMENT, WCG

3

DIVERSIFY SITE SELECTION

Even as diverse audiences become more aware of clinical research, as Bye said, limited access can complicate enrollment efforts. He emphasized that this, in part, linked back to selecting sites: If the sites where diverse patients receive care are also doing the research, studies, in turn, become more accessible. All too often, though, that's not how it works.

"There's a need for clinical research sites and investigators who serve these broader populations," he said. "At the same time you're bringing patients to sites, the site needs to be brought to the patient. This requires sponsors to ensure that sites are engaged and that those sites have the resources (people, technology, process and time) to conduct trials."

"At the same time you're bringing patients to sites, the site needs to be brought to the patient. This requires sponsors to ensure sites are engaged, and that those sites have the resources (people, technology, process, and time) to conduct trials."

—AMY THUE, ASSOCIATE DIRECTOR, PROJECT MANAGEMENT, WCG

TURNING TO TECH

How the Right Platform Can Help

Innovations in data and analytics have helped to advance the tech ecosystem surrounding clinical trials. With the tech evolution, sponsors can be more intentional and selective when assessing fit-for-purpose tools to improve their process.

But as tech experts often caution around this topic, adding a tool just to have one creates unnecessary burdens on a site's study team. Any platforms that sponsors ask sites to use should be focused on the process and offer in-depth reporting as a key feature. Relevant data reporting enables sites to learn and know more about potential participants, thereby informing recruitment and retention strategies, Bye added.

"Sites have to understand the full participant journey," he said. "Where are these individuals coming from? How are they learning about the study? How are they getting to the study? What does it take from them to join the study and be part of it?"

Consolidating that rich information into a single, centralized patient and site identification platform gives a lot of power, he added.

"Sites have to understand the full patient journey. Where are these individuals coming from? How are they learning about the study? How are they getting to the study? What does it take from them to join the study and be part of it?"

—TYLER BYE, DIRECTOR OF PROGRAM STRATEGY AND PRODUCT DEVELOPMENT, WCG

"Otherwise, you're spending and wasting time trying to manually collect and combine that data," he said. "Technology can help sponsors live up to the fast pace of clinical research, but it has to be the right technology."

As a former study coordinator, Thue emphasized that any technology investments should consider the site experience — as well as key functions that can make study teams' lives easier.

"I lived and breathed in Excel, and I can tell you, spreadsheets don't do a fraction of what a purpose-built tool can," she said. "Excel doesn't track next action dates, it doesn't have dropdown criteria when a patient is disqualified, or anything else that makes the job easier."

"Using platforms that track patient eligibility, automate functions and otherwise remove burdens from sites — for example, self-screeners – can make the enrollment experience much less cumbersome," Thue added.

Even so, tech can't solve everything on its own without human expertise. This drives the need for expert and flexible partners like WCG that can facilitate, scale and support its implementation and ongoing use.

"You need individuals and well-equipped teams who understand the technology and its output so that you can make more actionable and informed decisions," Bye said.

"You need individuals and well-equipped teams who understand the technology and its output so that you can make more actionable and informed decisions."

—TYLER BYE, DIRECTOR OF PROGRAM STRATEGY AND PRODUCT DEVELOPMENT, WCG

Adapting to a Changing Era

Enrollment and recruitment remain a challenge, and increased public attention to trials adds another layer of complexity that needs to be managed. The higher awareness, if properly supported, could bolster interest in clinical trials. But at the same time, politicization and misinformation can set good intentions back.

By understanding the resistance and being sensitive to avoiding triggers, sponsors can help sites navigate the new normal for a faster, more effective study startup. Even so, studies struggle more than ever to meet the complexity and demands on participants and study teams. Confronting these challenges, sponsors will need to look toward practical solutions to overcome the barriers.

Best practices in this new moment include understanding that not all patient motivations are altruistic, and in promoting clinical trials, sponsors should work more to evangelize what's good about clinical research. Diversifying sites and patients can further help sponsors capitalize on shifting awareness trends while addressing the moral imperative of representation.

As sponsors implement these best practices, consider how technology powered by advanced data and analytics can help. By learning more about patients' unique challenges along their journeys, sites can address the opportunities of this changing era to get more people involved in research.

WCG is a global leader of solutions that measurably improve and accelerate clinical research. Biopharmaceutical and medical device companies, contract research organizations (CROs), research institutions, and sites partner with us for our unmatched expertise, data intelligence, and purpose-built technology to make informed decisions and optimize study outcomes, while maintaining the highest standards of human participant protection. WCG raises the bar by pioneering new concepts, reimagining processes, fostering compliance and safety, and empowering those who perform clinical trials to accelerate the delivery of medical therapies and devices that improve lives. For more information, please visit wcgclinical.com or follow us on Twitter @WCGClinical or LinkedIn.