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The power of choice: Why patient optionality is the key to advancing clinical research

Contents

Introduction

Brick-and-mortar clinical sites, which are typically situated within hospitals in urban areas, have traditionally been the main staple in sponsors' ability to drive clinical trials and enroll patients.

But in recent years, this has been changing. Necessity being the mother of invention, the trend for conducting some or all study activities outside of the traditional site and instead moving them closer to the participant's home accelerated during the pandemic as a means of delivering clinical research in a safer and more convenient way.

While the movement gained significant momentum during the pandemic when patients were isolating at home, clinical research is now evolving to harness a much wider range of settings, some of which are centered around local communities. With this comes the potential to move beyond one-size-fits-all studies, giving participants a greater degree of choice over how they wish to participate in research.

Figures obtained from GlobalData's enrollment module indicate that only 46% of clinical trials report meeting their enrollment targets. Conversely, GlobalData's Clinical Trials database indicates that just 2% of decentralized trials (studies that use virtual technologies and other remote processes such as mobile visits to assist with data collection, enrollment, dosing, and monitoring) have been withdrawn, suspended, or terminated due to low accrual rates. The good news is that, since the rise in decentralized and community research seen throughout the pandemic, there are clear signs that clinical trial sponsors are continuing to adopt these options into trial designs.

While 5.6% of clinical trials have featured a decentralized or community-based element since 2018, in the first seven months of 2024, 1,170 studies included one or more elements of decentralization in their trial protocol, according to GlobalData's Clinical Trials database. This reflects a total figure 26% higher than in the first seven months of 2023.

Since 2022, nontraditional players have entered the clinical trial space, providing sponsors with an even wider range of options when designing trials. As a result, they can achieve a broader geographic reach compared to traditional brick-and-mortar clinical sites, increasing the likelihood of enrolling and retaining larger, more diverse patient populations.

This whitepaper explores why this evolution in clinical trial models is so significant, including its ability to overcome longstanding barriers to clinical trial participation and address the need for more diverse representation in research. It will also discuss the burgeoning landscape for hybrid trial participation models and provide advice for how sponsors can take the next step in implementing participant optionality in trials.

Optionality matters

Historically, there have been barriers to trial enrollment and participation that can also affect clinical study retention rates. Data from the Center for Information and Study on Clinical Research Participation (CISCRP) found that the physical location/proximity of a research study site is one of the most important factors in a patient's decision to participate in a clinical trial. This is because many patients face significant travel times – in fact, 29% of the trial participants surveyed in CISCRP's 2023 Perceptions & Insights study had to travel more than an hour each way to get to their study site. When asked to imagine partaking in a trial with a follow-up period lasting three to five years, two-thirds of participants said that the ability to complete study visits closer to their home would be the most important factor in keeping them enrolled.

In addition to the challenges posed by the limited geographic reach of traditional brick-and-mortar sites, which can negatively impact trial enrollment and retention rates, there are other significant barriers. These include a lack of awareness among participants about available trials, as well as considerable challenges related to the overall burden of participating in a study. This is typically influenced by the number of required visits to a clinical site, the arrangement of adequate transportation, scheduling conflicts, and more.

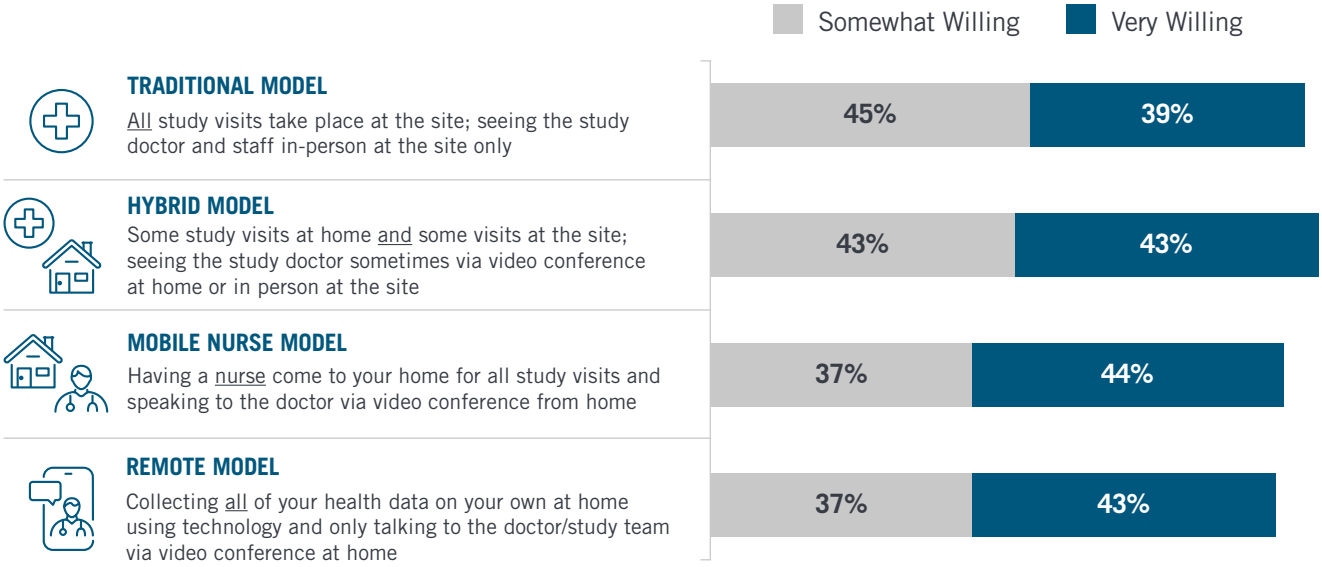
These challenges may be extrapolated further in geriatric and pediatric patient populations, or those reliant on family members/caregivers to assist them in meeting the requirements necessary for successful trial participation.

The implementation of hybrid clinical trial designs, which may include options like community research sites or mobile visits for certain or potentially all aspects of a clinical trial protocol, not only helps to alleviate many of the common barriers and constraints towards patient participation, but in turn serves to expand the overall geographic reach of a study, enabling trial sponsors to reach broader patient populations.

Understanding the options

According to CISCRP's 2023 survey, patients continue to show a strong willingness to participate in a range of clinical research models, as illustrated in the chart below. As the demand for alternative options becomes clear, the community research ecosystem is evolving to meet it.

How willing would you be to participate in each of the following types of clinical research studies?



Source: CISCRP

Sample Size = 12,017 | Base: All respondents

Mobile research sites

Mobile research sites are often used as a way of expanding access in specific, underrepresented communities. PCM Trials company EmVenio Research's mobile research sites enter communities with long-term placement in mind. The company locates its mobile site locations strategically, taking into account population demographics, disease prevalence, socioeconomic factors, healthcare access, and the competitive landscape.

Customized to suit specific or multiple clinical trials, mobile research sites support a full range of protocol procedures, from standard to more complex needs, serving as a hub that can handle aspects of clinical trials including patient enrollment, data collection, and follow-up visits.

Community research centers

In 2024, to further bolster the network of options available for sponsors to offer trial participants, EmVenio Research entered a partnership with award-winning national health system Prime Healthcare, allowing the company to establish clinical research centers at Prime Healthcare hospitals across the United States and offer Prime Healthcare patients and community members improved access to clinical trials.

With the Prime Healthcare collaboration and the merger between EmVenio Research and PCM Trials, the companies can now operate as a unified organization to explore different ways to provide expanded optionality for trial participation.

"We're able to do this with EmVenio's research centers, which are really new, traditional brick-and-mortar sites within the community setting and how we're able to take mobile sites and drive further into the community to allow for research closer to home," explains Thad Wolfram, Chief Strategy Officer, EmVenio Research.

Wolfram goes on to explain that patient optionality is a case of bringing the entire platform of site options, all operating under the same principal investigator and with the same research team and staff, to create a comprehensive way to deliver patient-centric trials.

Mobile visits

Further supplementing mobile research sites and community research centers for clinical trial activities, another option in the community research toolkit is the provision of mobile clinicians, provided by companies like PCM Trials, to enable sponsors to offer visits directly to patients' homes.

Mobile visits represent an especially vital offering for trials involving geriatric patients, an underrepresented patient population due to patients in the 65+ age group being more likely to have challenges in getting to the study center.[1]

With the traditional trial model proving burdensome to children and their caregivers, who often must take time off school and work to travel to the clinical site regularly, researchers are also beginning to see the value of community research in pediatrics. In 2022, 9.6% of all pediatric trials used at least one element of decentralized or community-based research such as mobile visits or remote patient monitoring, as per GlobalData's Clinical Trials database.

"PCM Trials has a dedicated team of professionals, and that team helps to identify clinicians who have been vetted by experience and education to conduct trial services in a participant's home," explains Tajuana Barron, Vice President of project management at PCM Trials.

"After performing rigorous background checks, we hire clinicians who undergo GCP training and then get assigned to a study based on the specific needs of that particular protocol, thereby ensuring that we are able to place the right hands with the right equipment, and that person is going to show up at the right place and conduct the visit on time."

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– Tajuana Barron, Vice President of project management at PCM Trials

Research by GlobalData indicates that mobile visits have a positive impact on clinical trial outcomes in several key regards, with research finding that trials utilizing mobile visits experienced expedited trial enrollment times by an average of 3.14 months compared to those without.[2] Studies with a mobile visit element have also been found to be 41% more likely to complete early compared to similar trials in which mobile visits were not utilized.

For participant retention rates, by comparing similar Phase II and III trials, research by GlobalData has also found that sponsors who used mobile visits in their trial design saw an almost half or better reduction in drop-out rates.[3]

"Some visits will always need to take place at a traditional brick-and-mortar site, but some visits can actually take place in the community, maybe at a mobile site, and further mobile clinicians can conduct those visits in the home," says Wolfram. "We also see increasing use of technology to allow for ongoing data collection, or to ease the data collection that takes place throughout the course of a study."

[1] https://pmc.ncbi.nlm.nih.gov/articles/PMC4640010/
[2] https://www.clinicaltrialsarena.com/sponsored/remote-nursing-faster-study-results/
[3] https://www.clinicaltrialsarena.com/sponsored/how-to-improve-patient-engagement-and-retention-rates-with-mobile-nurse-visits/

Meeting the diversity mandate

A lack of diversity has been a longstanding issue in the clinical trial space – a significant problem given that certain treatments under development may have different outcomes among different ethnic and racial groups.

Past research by the US Food and Drug Administration (FDA) has indicated that Black Americans, for example, who make up 13.4% of the U.S. population, only account for roughly 5% of trial participation. In addition, GlobalData has found that Black participants are underrepresented in most clinical studies, with severe underrepresentation in oncology studies, comprising just 3% of participants in global clinical trials from 2013 to 2022.[4]

Hybrid trials have the ability to change this. Data from the past seven years has, for example, shown that Hispanic and Latino participants are significantly more likely to be included in trials with a mobile visit component.[5]

The FDA's recent publication of guidelines outlining the need for more diverse representation in certain clinical studies, means that trial diversity metrics may now play an influential factor in a drug's approval.

Since coming together in 2024, PCM Trials and EmVenio Research's aim has been to strengthen the combined organization's abilities to recruit and retain diverse populations in clinical trials.

"The data that is collected in a clinical trial needs to be representative of the eventual population that any vaccines or therapeutics will be made available to," says Wolfram.

"It's important to ensure that we are thinking holistically about right representation across the population, but also taking both the therapeutic area and indication-specific view on what part of the population is most impacted by a given disease and will therefore benefit the most from a new medicine."

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– Thad Wolfram, Chief Strategy Officer, EmVenio Research, a PCM Trials company

Two of the Prime centers have been established in the Dallas and Atlanta regions and are situated in close proximity to two of EmVenio's existing research sites.

Wolfram says this now gives the company the ability to operate in a radius around these centers – something which could not historically be done.

"We're also looking at this as an opportunity to establish greenfield sites, as we're standing up in Kansas City and in Garden City outside of Detroit," Wolfram says. "Ultimately, we're thinking about how we can expand the overall ecosystem of access to clinical research trials."

Over the past few years, these efforts have led the company toward achieving 98.5% of its study enrollment targets. According to Wolfram, they have resulted in a 92% trial retention rate with 44.7% of the patients that enrolled coming from minority populations. In the last six studies that EmVenio Research supported, the figure for minority enrollment approached 60%, evidencing that increased optionality by embedding sites into local communities is having an appreciable effect on the ability of the company to satisfy the FDA's diversity requirements.

[4] https://www.clinicaltrialsarena.com/analyst-comment/black-participants-oncology-studies/
[5] https://www.clinicaltrialsarena.com/sponsored/will-mobile-visits-help-the-clinical-trials-industry-meet-its-diversity-goals/

Moving forward with hybrid trials

While it is possible for active studies that are having participation-related challenges to amend protocols at the mid-way point to add in more participant optionality, making such changes requires a protocol amendment that must be approved by the FDA.

With this in mind, PCM Trials advises that sponsors looking into optionality for their trials should plan carefully from the outset so that their study and protocol designs are set up to allow for different options.

According to PCM Trials, the site options available in a trial should be driven by patients; sponsors should empower participants to function as decision-makers, deciding what option works best for them and allowing their viewpoints to inform what optionality would be advisable for a given trial design to include.

In conducting their research around the ability to facilitate hybrid trials ahead of trial initiation, sponsors may consult with companies like PCM Trials, which has the available infrastructure and resources to help provide expanded patient access. PCM Trials and EmVenio Research can equip sponsors with high-quality, validated strategies for broadening the reach of their clinical trials and improving participant retention.

For example, in a rare disease study EmVenio Research was involved in, a participant did not want to participate in a home visit and was going to exit the study; however, they were open to protocol visits performed at a mobile research site. By bringing a mobile site into the vicinity of the patient for the visit, this patient chose to remain in the study.

Wolfram views one of the key challenges around hybrid trials as the need to improve the industry's receptiveness to other ways of interacting with participants.

He comments: "It took a while for telemedicine to gain acceptance, but it was accelerated during the Covid-19 pandemic. Similarly, the necessity of remote visits in clinical trials during the pandemic showed many that it works."

Conclusion

The advantages of hybrid trials are clear – by incorporating more community-based elements into trial designs, sponsors can expand the reach of clinical research to a broader patient base, improve participant retention, and ensure that clinical data is collected from a more diverse group of patients. To find out more about community research methodologies and the options available for your upcoming trial, please get in touch with our experts today.

PCM Trials has been leading the way in mobile research since 2008. To learn more or discuss an upcoming trial and how a decentralized or hybrid strategy can improve your trial's outcome, call **888.628.9707** or **visit www.pcmtrials.com/request-for-proposal** to submit your RFP.

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