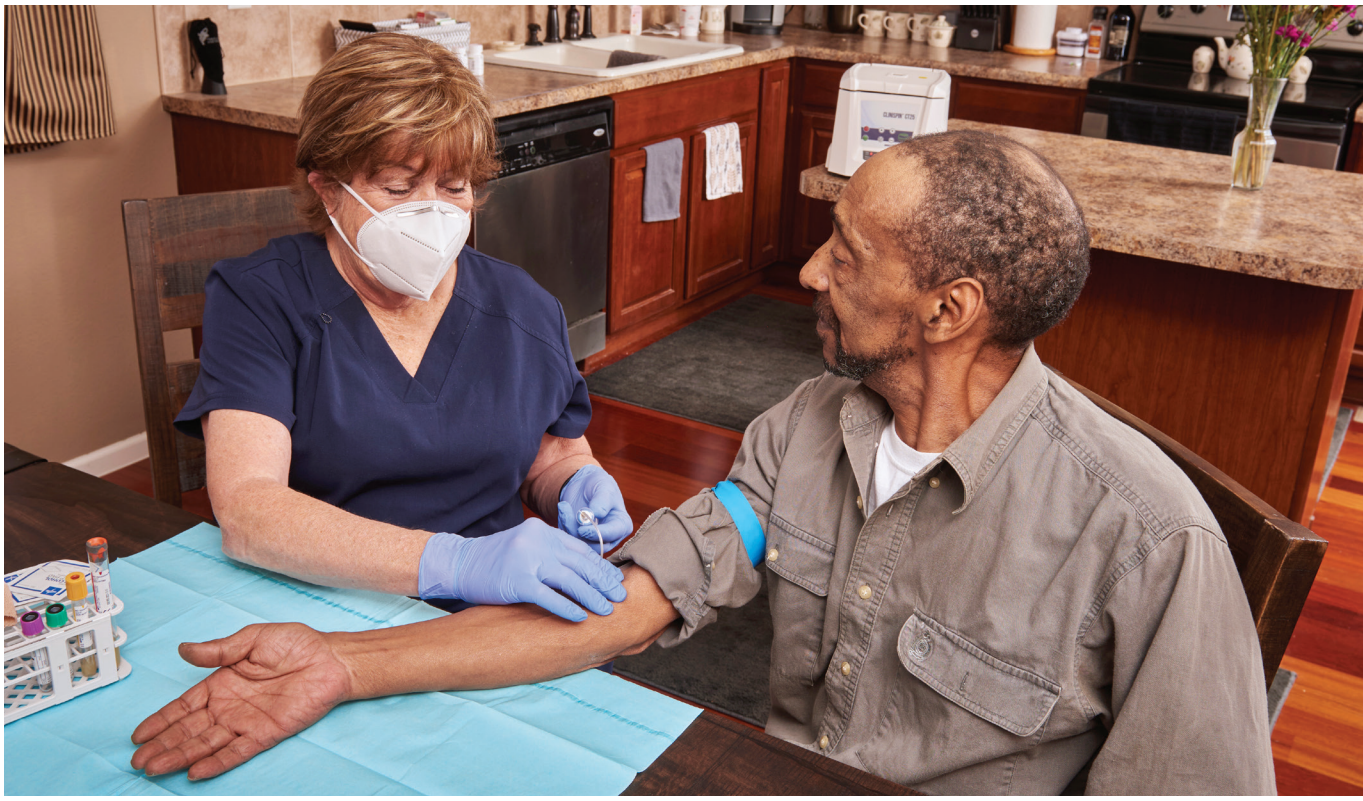
PCM TRIALS
QUALITY MOBILE RESEARCH

The FDA Steps Up Pressure on Sponsors to Increase Diversity in Clinical Trials: How Decentralized Trials Can Help

EXECUTIVE SUMMARY

The FDA has been advocating for increased diversity in clinical trials for decades but, by its own account, little progress has been made and certain groups remain woefully underrepresented in many studies. But could we now be at a turning point where talk about increasing diversity and inclusiveness translates into action and real change occurs? All indications point to “yes”, with the FDA issuing a second set of guidelines for how study sponsors can increase racial and ethnic diversity in clinical trials. Such guidance is causing many in the trials industry to look for more opportunities to incorporate a decentralized trial option into their protocols, as DCTs can help to recruit and retain more diverse patient populations.



THE CURRENT STATE

According to the FDA's most recent five-year summary and analysis of clinical trial participation and demographics, three out of four clinical trial participants (75%) were white, 11% were Asian, and only 7% were Black or African American. These are just some of many statistics that document the underrepresentation of minorities in clinical trials.

This underrepresentation is problematic because, as the FDA said in its most recent guidance:

> *"It is known that biological differences exist in how people respond to certain therapies. For example, variations in genetic coding can make a treatment more or less toxic for one racial or ethnic group than another. These variations can also make drugs like antidepressants and blood-pressure medications less effective for certain groups."*

THE IMPETUS FOR CHANGE

Several events have converged to create an environment where progress to increase diversity in clinical trials seems more possible now than at any time in history.

- Racial and ethnic minority groups were more likely to get sick and die from COVID-19 bringing racial injustice and health disparities to the forefront of people's minds.
- Vaccine hesitancy was high among Black adults, with 35% saying they definitely or probably would not get vaccinated and about half of those saying a major reason was that they don't trust vaccines in general.
- This led to calls from scientists, including Dr. Anthony Fauci, for drug companies to significantly increase minority participation in clinical trials for the vaccines.
- And just as more minority participation could increase confidence and uptake of vaccines, the same holds true for other medicinal therapies. If individuals know a study included a meaningful number of participants who share their racial and ethnic background, it stands to reason that they would have a greater degree of trust in the safety and efficacy of the treatment and would be more likely to use it, thereby helping to reduce health disparities.

These events have created momentum to the point where it appears that finally the time has come to meaningfully increase racial and ethnic diversity in clinical trials. Decentralized clinical trial methods are critical to achieving that goal.

HOW DECENTRALIZED CLINICAL TRIAL METHODS CAN HELP SPONSORS INCREASE DIVERSITY IN CLINICAL TRIALS

Incorporating patient-centric, decentralized clinical trial methods into their study designs can enable sponsors and CROs to increase diversity by overcoming several of the barriers to participation inherent in site-based clinical trials.

Taking the study to the patient instead of requiring the patient to go to the study site can help increase recruitment and retention by making participation more convenient, less costly and less time-consuming for the participant. A patient who lives far from a medical center may lack the financial resources to travel to a distant site—a trip that may incur airfare, on-the-ground transportation and lodging expenses.

Even if a person lives reasonably close to a site, the visits still may be unduly burdensome if they require the participant to take time off work to travel to and from the site on multiple occasions and pay for transportation, parking, daycare for family members, meals and other associated expenses. Some participants may also lack the work flexibility to go to a site during the hours the site is open. The wait times can also add to the burden. And for those participants who are ill, the exposure to bacteria or other environmental pathogens enroute to site visits can increase their risk of infection, which may impede their ability to receive certain therapies on the prescribed schedule, jeopardizing the study.

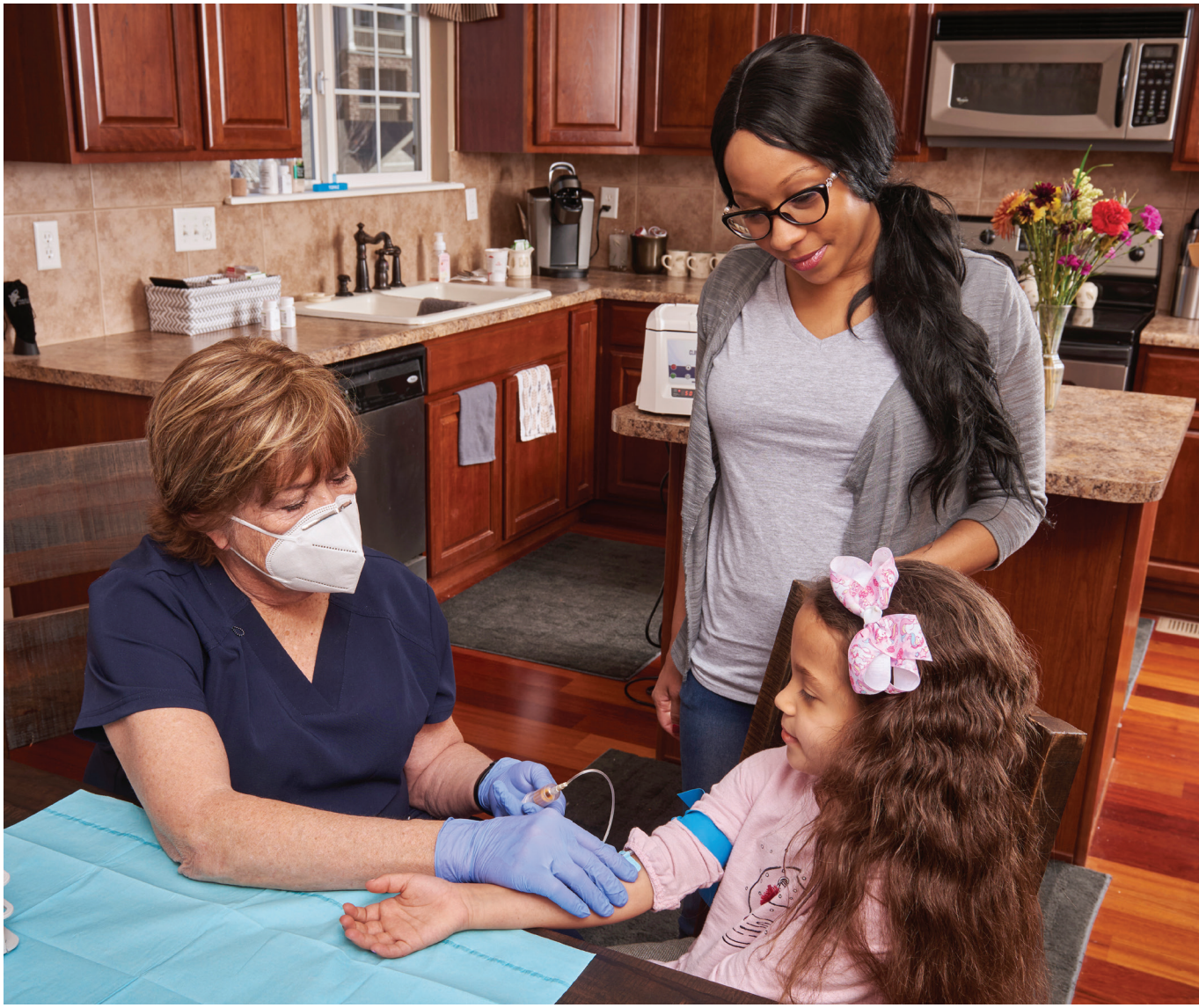
The FDA is aware of the role that decentralized clinical trial methods can play in increasing diversity in clinical trials. In its 2022 guidance, the FDA calls on sponsors to *"describe in detail the operational measures they will take to enroll and retain underrepresented racial and ethnic participants"* including their strategies for *"reducing burdens due to trial/study design/conduct (e.g. number/frequency of study-related procedures)."*

In its November 2020 guidance, the FDA also encouraged sponsors to make participation less burdensome and recommended that sponsors *"consider the use of mobile medical professionals, such as nurses and phlebotomists, to visit participants at their locations instead of requiring participants to visit distant clinical trial sites…"*

In addition to reducing the burden, mobile medical professionals also can reduce anxiety among participants, especially when they live in the same communities as the study participants, look like them, and visit them in the familiar environment of their homes. This enhances the comfort level for participants, as compared to what they may experience travelling to research sites which often are located in unfamiliar neighborhoods far from where they live, and where they have to interface with unfamiliar personnel in an institutional setting that may feel cold and intimidating.

PCM Trials, a leading provider of mobile research, employs Certified Mobile Research Nurses (CMRNs) who are specially trained to provide nursing services specific to clinical trials. They travel wherever and whenever it is most convenient for the patient, which increases trial accessibility and makes it possible for sponsors to recruit a more diverse set of participants. The nurses provide a full range of clinical activities that can be safely delivered with portable equipment such as the dosing of the medication or investigational medical product by infusion, injection, and other routes of administration; blood draws, sample collection and logistics; clinical assessment and observation; investigational device management; patient education and training and adverse event monitoring; and the operation of centrifuges, EKGs, and other equipment. PCM Trials also provides operational support to study sponsors.

To learn more about how decentralized clinical trial methods can help you comply with FDA guidance to increase diversity in clinical trials, contact PCM Trials or visit www.pcmtrials.com/request-for-proposal to submit an RFP today.



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