PCM TRIALS
QUALITY MOBILE RESEARCH

Decentralized Trials Are Better Understood, But 5 Misconceptions Persist

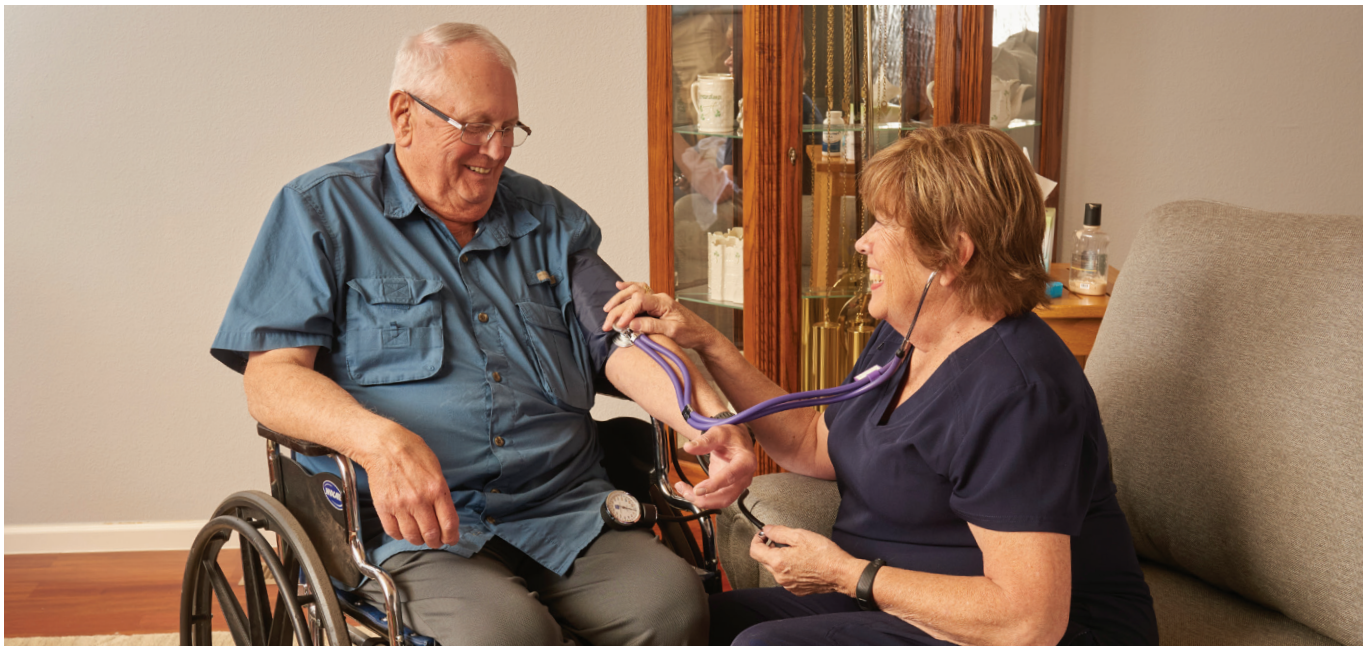
EXECUTIVE SUMMARY

Even though decentralized clinical trials (DCTs) have existed for almost 20 years, many sponsors and CROs hesitated to employ them for a variety of reasons, including discomfort due to a lack of familiarity. But the COVID-19 pandemic changed that.

Sponsors who would never have considered a DCT in the past were suddenly flocking to DCT service providers in desperate efforts to rescue their drug trials. As a result, most sponsors and CROs are now familiar with DCTs.

Despite the progress, persistent misconceptions remain and are standing in the way of wider adoption of DCTs and the benefits they bring, including making potentially life-saving drugs more accessible to a more diverse range of trial participants.

Five reasons some CROs and sponsors still hesitate to use DCT methods include concerns about safety, complexity, capacity, control and cost. Here are the concerns and how one provider of mobile research services, PCM Trials, addresses them.



CONCERN 1: SAFETY

As just one example, consider the integrity of the investigational product. At a site, it's stored in a secured and segregated location such as a locked cabinet and has a known chain of custody. With DCT, a sponsor may ask, who is qualified to handle the IP? How will it be delivered to the patient? How can they be certain that the right IP and right dose is administered to the right patient at the right time, and done so safely? What happens if a trial participant has an adverse event?

"If a trial is not done at the physical site, within my view, it won't be safe and may not adhere to protocol."

Response: Stringent operating procedures are put in place to address these and all safety and adherence concerns, and highly trained mobile research nurses ensure protocols are strictly followed to identical standards as physical sites. For example, PCM Trials created a unique Certified Mobile Research Nurse (CMRN) certification to ensure high quality clinical research support. It hires only RNs, and as part of its rigorous hiring and onboarding process, CMRNs complete good clinical practice (GCP) training and are regularly assessed to ensure that their certifications remain up to date. The PI reviews and approves the credentials of CMRNs under their supervision before mobile visits can take place. CMRNs are also specially trained to conduct clinical research in a non-site setting, independently yet under remote oversight by the same principal investigators as at physical sites. CMRNs have been trained to watch for and anticipate patients' safety issues to meet the high standards of both PCM Trials and sponsors. Additionally, they receive protocol-specific training for each study so that every patient encounter adheres to the protocol.

CONCERN 2: COMPLEXITY

Some investigators believe that certain studies are too complex to be done anywhere but at a traditional site, with its extensive equipment and staffing.

"DCT methods cannot be used for complex clinical trials, such as oncology."

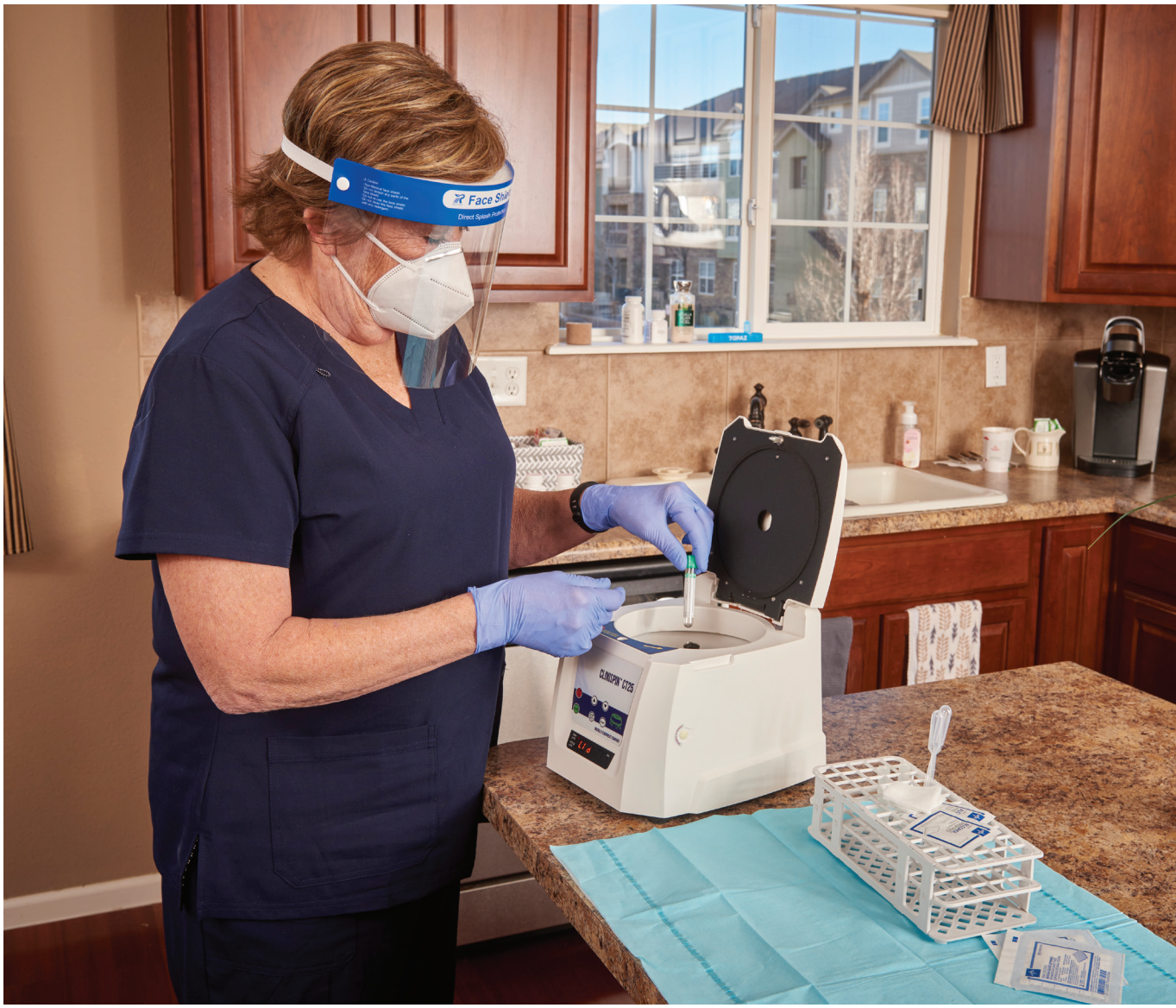
Response: Sponsors and CROs might be surprised to learn the wide range of services that can be performed by certified mobile research nurses at the patient's home. For example, many of today's oncology trials focus on cell therapy, transplant, and personalized medicine. Some actions such as scans and chemotherapy delivery must be done at the site, but many new treatments such as transplants require a rigorous multiday, pre-procedure conditioning regimen that can be done very effectively and efficiently in the patient's home. This enables the often-immunocompromised trial participant to remain at home for as long as possible ahead of complex and very expensive procedures such as apheresis, thereby reducing the risk that the patient will fall ill in the days leading up to it by being exposed to bacteria or viruses while traveling to and from the site. PCM CMRNs regularly conduct many other visits with complex protocols that sponsors who have not frequently employed DCT may find surprising.

CONCERN 3: CAPACITY

Many care providers or adjacent other vendors ramped up or entered the industry during the pandemic by contracting with nursing agencies to do home visits for clinical trials, but as the surge subsided, most could not or did not maintain the capacity as their businesses reverted to a normal state.

"A DCT provider would never be able to provide enough nurses to serve all of my patients."

Response: PCM Trials' only service offering is to provide mobile nurse visits, giving it a singular focus that enables it to avoid being distracted by competing priorities. And directly recruiting, hiring, training and managing its own nurses gives PCM Trials more control over its capacity than it would have if it relied on nursing agencies which may have more transient staff as nurses roll on and off. In addition to a secure capacity pipeline, sponsors and CROs receive the benefit of a service provider that has direct relationships with nurses that span years.



CONCERN 4: CONTROL

Clinical research by its nature is difficult, risky and expensive, so it would be understandable to fear turning over control to a third-party.

"If I use a DCT service provider, I will have to give up too much control."

Response: Sponsors and investigators retain complete control over the study, even when adopting DCT approaches. PCM Trials takes a collaborative approach, using its expertise to adhere to a protocol for home visits but relying on the sponsor for scientific, medical and other expertise. Even though all or some of the visits may be remote, the site and PI retain complete control of remote visits, with remote visits coordinated with site visits, and the investigational product's distribution tightly managed by the research team and under the purview of the principal investigator. Many visits include a telemedicine component where the principal investigator can monitor and guide the nurse and speak directly to the patient.

CONCERN 5: COST

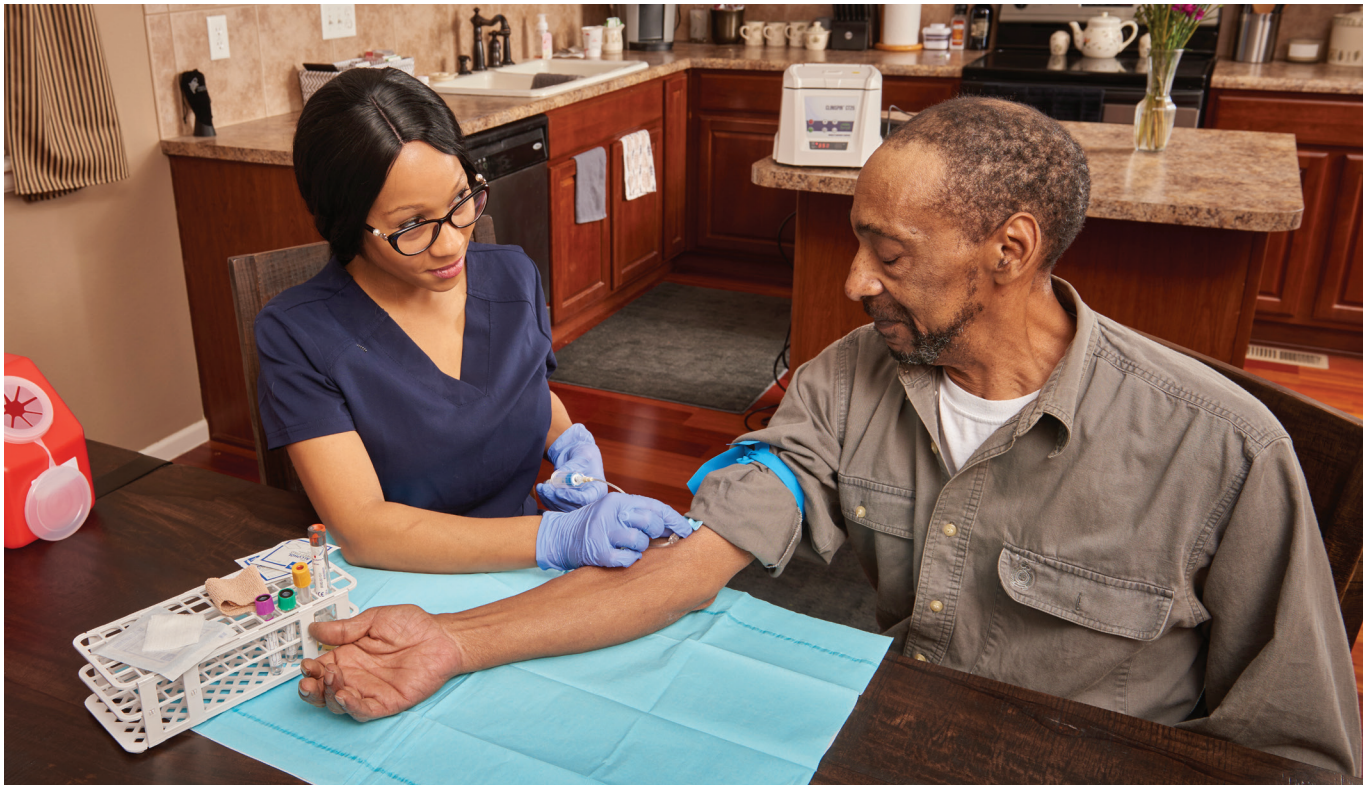
Employing dozens or more mobile research nurses to visit each patient at their own home seems like it would be more expensive.

"Decentralized Clinical Trials are more expensive than traditional site-based trials."

Response: There is no one-size-fits-all answer when it comes to cost, but a decentralized trial has some inherent cost advantages. For example, chemotherapy patients often need to have their blood drawn a specific number of hours following a treatment. Such blood draws done at a traditional site may require extended office hours, phlebotomists and lab access, none of which would be required with a home visit. In many types of studies such as those involving rare diseases, it is often more cost effective to engage a few sites and extend their reach with mobile research nurses than to engage many sites, each with one or two study participants recruited from only the local community. Further indications of potential cost advantages include a recent survey which found a plurality of respondents expect DCTs to be less costly than site-based trials. In addition, a lead investigator on the largest nationwide Parkinson's study of its kind estimates a cost savings of 80% per participant compared with a similar trial conducted at a traditional site. Another cost consideration is the value of retention. Participants are less likely to drop out of a patient-centric trial that makes participation easy and convenient, versus one that requires frequent and potentially disruptive travel to a distant clinical site.

With so much at stake in clinical research, it's natural to be wary of methods that involve activities that take place beyond the walls of traditional sites, but the often overlooked fact is that decentralized clinical trials extend the patient reach and recruitment success of traditional sites, improve the patient experience, help with patient engagement, and are proven to yield results in the form of FDA approvals over nearly two decades.

Since the first home visit was deployed in a clinical trial for a hemophiliac study in 2003, PCM Trials has worked with more than half of the top 20 global pharmaceutical companies. To answer your questions about an upcoming trial and to discuss how a decentralized strategy can improve your trial's outcome, call 888-628-9707 or visit www.pcmtrials.com/request-for-proposal.



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