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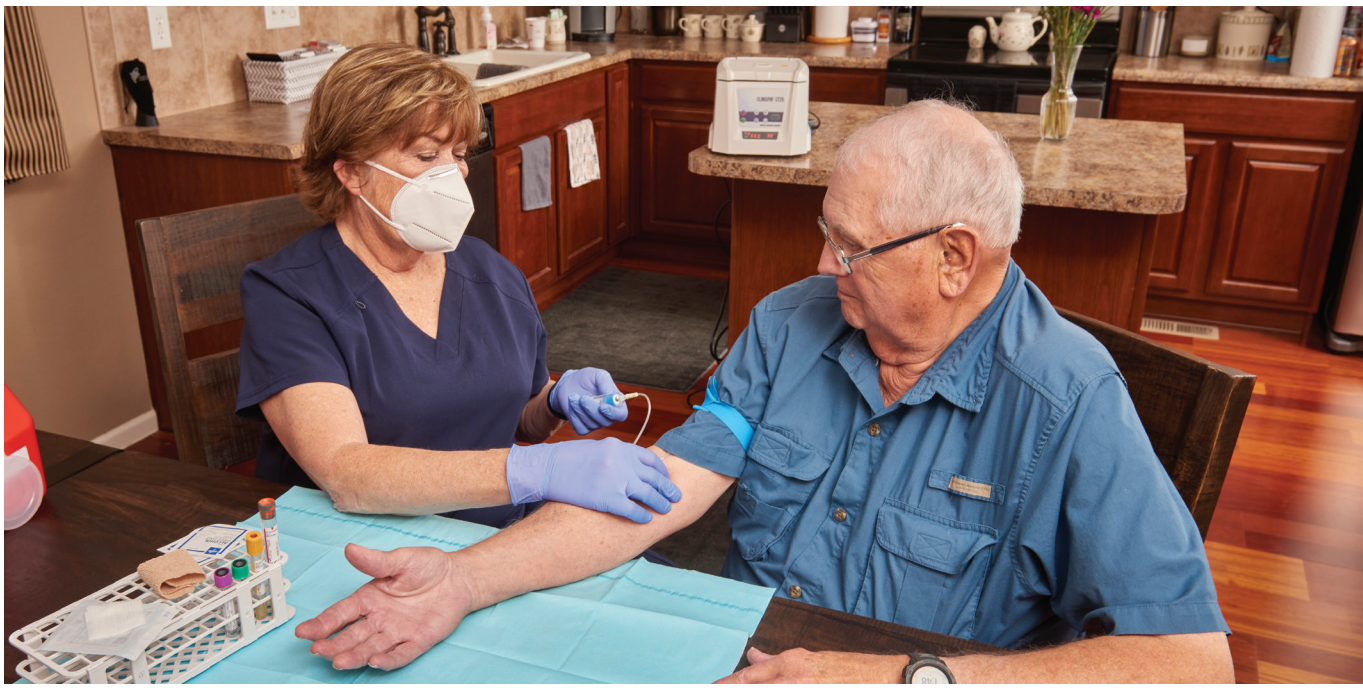
DCT Planning Checklist: Your Guide to Ensuring a Successful Decentralized or Hybrid Trial

Executive Summary

Even before the COVID-19 pandemic spotlighted the benefits of decentralized clinical trials (DCTs), their use was becoming more commonplace. After witnessing the ability of DCTs to rescue a number of clinical trials that were in jeopardy as a result of participants being unwilling or unable to safely travel to clinical sites, more sponsors and CROs are taking note of how a mobile approach could benefit their trials.

Whether used exclusively or as part of a hybrid approach in conjunction with traditional trial methods at clinical sites, the patient-centric nature of DCTs can enable investigators to more easily recruit and retain a diverse patient population. DCTs can't, however, yield their full spectrum of advantages if not implemented with the proper planning and attention to detail.



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The following checklist can help guide sponsors and CROs toward a successful decentralized trial or effective integration of a hybrid approach.

✓ Plan Ahead

Incorporate mobile research into the trial protocol at an early stage.

Too often mobile research is considered as an afterthought or merely as an add-on to a traditional program. Sometimes it is not seriously considered until after a trial is in jeopardy because of low recruitment and/or retention. This presents several complications that may delay the trial or threaten its success.

Primarily, it may necessitate creating an amendment to the protocol if the original protocol did not outline how the trial would be conducted using a DCT or hybrid approach. Anyone who has ever had to file an amendment can attest to the extra effort that it involves.

Key questions to consider:

- *Will the trial be set up as fully decentralized or part of a hybrid model?*
- *How should you coordinate with clinical sites to leverage home visits?*
- *Does the protocol being used to secure trial approval clearly call out the use of home visits?*

✓ Know Your Partner

Conduct thorough due diligence on the DCT provider to ensure that its nurses have good clinical practice (GCP) training and a proven process for training on study protocols to maintain the integrity and consistency of the data.

Mobile visits can yield exceptionally high-quality data. But the results are only as good as the clinical professionals who are gathering it. It's important to confirm that the mobile nurses involved in the trial have received the appropriate level of training that is specific to clinical trials in general, as well as the individual study. If proper training is not provided and the mobile nurses don't follow the necessary protocols, the trial may be delayed due to the need to exclude some datapoints.

Key questions to consider:

- *How does the partner source its mobile nurses?*
- *What type of training do the mobile nurses receive?*
- *How does the partner ensure that its mobile nurses are following specified protocols for the clinical trial?*

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✓ Consider Patient Input

Solicit patient input upfront and create a process for capturing feedback during the trial.

A common problem is that sponsors, CROs or even the clinical sites may make assumptions about what's easiest and best for patients without first consulting them. Often the opposite of what is assumed is true. In order to optimize retention, it's vital to have an open dialogue with patients early in the process so you can consider their needs in the trial design, while still meeting the requirements of the protocol. You should also have a process for a participant to provide feedback during the trial, and for elevating and applying this feedback if there's an issue that is impacting compliance or retention.

Key questions to consider:

- *How much flexibility is there in the trial to accommodate patient schedules and requests?*
- *What are likely the greatest challenges or barriers for patient participation, i.e., number of times a day sugar levels must be checked, restrictive diet, amount of time expended, etc.?*
- *Is there a mechanism or process in place to gather patient feedback about their site visit experience, as well as how mobile visits can supplement it?*

✓ Anticipate Issues

Consider all logistics of the trial and adapt appropriately for mobile research.

It's important to picture what the trial will look like in the patients' homes and ensure that the trial requirements can be consistently met in a remote location. For example, if specialized equipment needs to be used regularly by the patients as part of the trial, it's critical to ensure that there is sufficient space in the patient's home or apartment to accommodate the equipment. If telehealth visits are written into the protocol, as another example, patients must have reliable Internet access.

Key questions to consider:

- *What equipment or special products need to be in the home to conduct the trial?*
- *Does the patient need access to various technologies, e.g., Internet, etc.?*
- *What is the threshold for needing to alert sites or sponsors of issues?*

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✓ Ensure Data Quality

Identify procedures for monitoring decentralized data to ensure its integrity.

A concern sometimes expressed by sponsors, CROs, and clinical sites is the lack of control over data acquired off-site. It is important to include in the protocol specific policies and procedures that allow for ongoing review and monitoring of the data, as well as define parameters for patient safety oversight monitoring. Companies that have been providing mobile research for some time are likely already familiar with best practices in this area, so there is no need to recreate the wheel.

Key questions to consider:

- *What procedures does the partner have in place to help ensure data quality?*
- *What type of experience and track record does the partner have with similar trials?*
- *How are discrepancies or questions reported?*

✓ Educate the Sites

Ensure sites involved in the clinical trial understand the benefits of DCT and are prepared to fully leverage the use of home visits.

Clinical sites often don't take advantage of home visits when given the option to do so. There are many reasons for this. Most often it's because they are not fully familiar with how the option works and are apprehensive about trying something new. They may be concerned about study data consistency or wonder if it will be more complicated to offer mobile and in-clinic visits.

The reality, however, is that by utilizing the home option, they will likely enroll more people at a faster rate. In addition, if they start the home visit option earlier, there is more time to identify and preempt potential issues. Clinical sites should be educated on the advantages home visits provide for the sites themselves, the sponsor/CRO, and the patients, and ensure that any common misperceptions are dispelled. Only then can they take full advantage of the benefits of a hybrid approach.

Key questions to consider:

- *Do the various sites have prior experience with a decentralized or hybrid approach?*
- *What questions or concerns have the sites raised relative to home visits?*
- *What additional support services are provided by the DCT partner?*

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✓ Communicate Regularly

Develop a plan to ensure all parties involved in the trial receive regular communications on trial progress, challenges, and changes.

Although trial protocols are very detailed, the success of any trial comes down to the quality of communication that everyone receives, including the sites and the mobile nurses. Thorough, consistent and regular communication is essential so that everyone accurately understands the expectations and goals of the trial. This will help ensure consistency of results between what is gathered at the clinical sites and what is gathered remotely.

Key questions to consider:

- *How will the sites and DCT partner communicate with each other?*
- *Is there a procedure in place to address questions or concerns on an ongoing basis?*
- *How often will various stakeholders mutually update each other on new developments?*

✓ Offer Consistently

Whenever possible, offer home visit options for trial and follow up.

There have been cases where patients are given the option to have home visits for the trial but are then asked to come to the clinical sites for follow up. This change in procedure can place an undue burden on patients. If mobile nurses are offered during the trial, it's best to continue to offer that option during the follow-up period.

Key questions to consider:

- *Can follow-up visits be conducted via mobile nurses?*
- *What is the tradeoff in patient centricity if they are required to visit a site for follow up?*
- *How long is the follow-up period, and what are the risks involved if the patient moves to another city and the sites are no longer easily accessible?*

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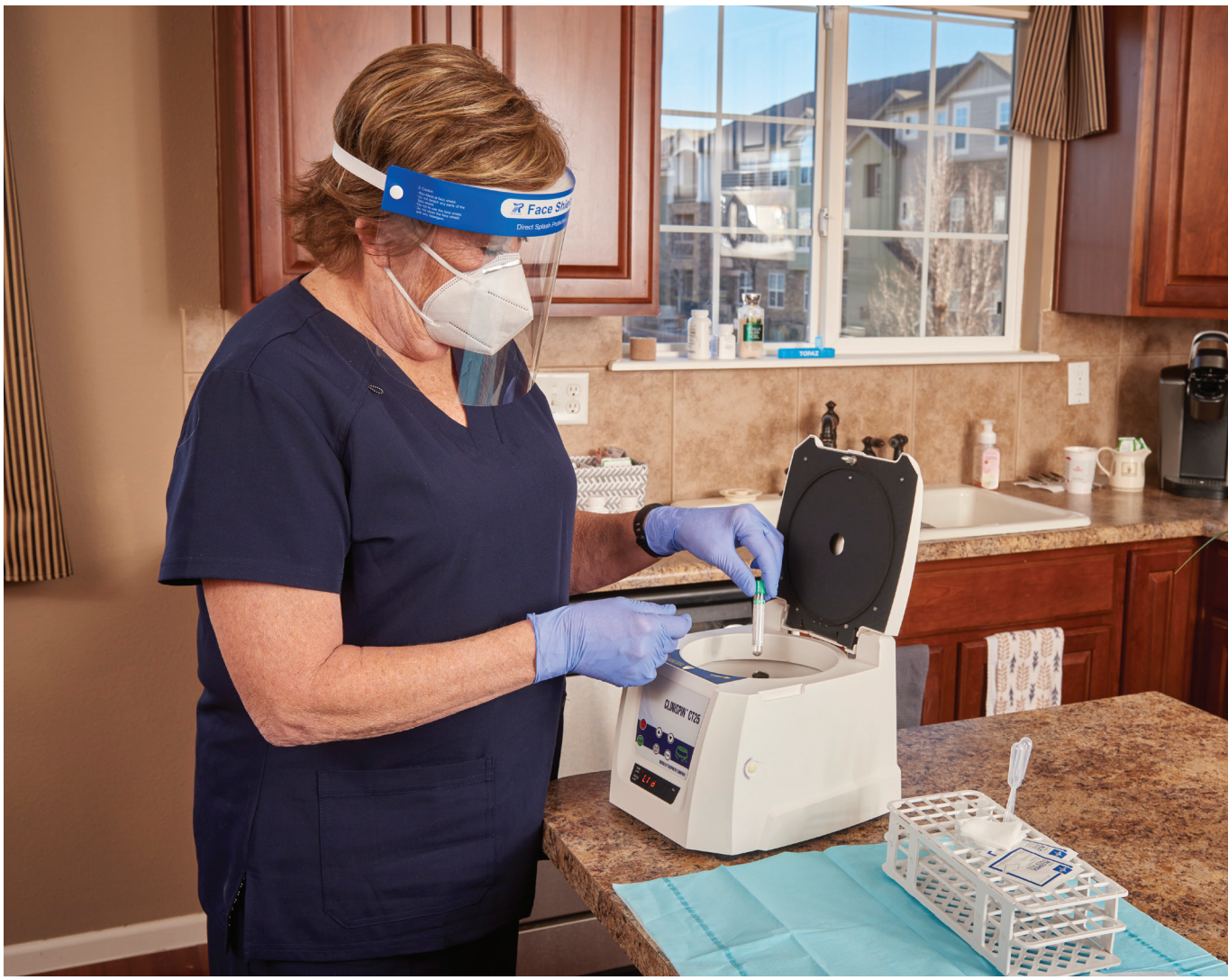
About PCM Trials

PCM Trials is leading the global shift toward decentralized clinical trials by bringing clinical research to patients, wherever and whenever it is most convenient for them. PCM Trials directly recruits, trains, certifies, and manages Certified Mobile Research Nurses (CMRNs) to ensure each visit meets the highest standards for data quality and patient experience. By reducing the barriers to participation, PCM Trials' mobile nurses support study recruitment, retention, adherence, and diversity. PCM Trials is an independent company headquartered in Denver, Colorado, with European operations based out of the UK, and has conducted more quality mobile research visits than any specialized providers in Europe, North America, and Asia Pacific.

Learn more at www.pcmtrials.com.

To 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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