



association for **clinical data management**

Top considerations for Decentralised Clinical Trials (DCT) in data management

Authors: Lauren Alani, Richard Moore, Doug Bain, Natalia Sofia, Jennifer Bradford,
Alan Yeoman, Emma Wrixon, Santosh Karthikeyan Viswanathan



Top considerations for DCT in data management

Decentralised Clinical Trials (DCT) offer an alternative approach to traditional brick and mortar studies, which can utilise telemedicine and technology-based solutions that may enable sponsors to access new data insights. They have become increasingly popular throughout the pandemic as a means to allow clinical trials to continue to take place throughout periods of lockdown. Some patients may also find it easier to take part in clinical trials if they either do not have to visit a site or can reduce the number of required visits. DCTs could positively impact the various stakeholders of the clinical trial ecosystem.

To provide some examples, sponsors might find they can accelerate clinical development by receiving greater enrolment, which may also offer a better representation of the total patient population, and they could develop a stronger evidence package than traditional trials. Additionally, when it comes to patients, DCTs can possibly offer a more streamlined experience, reduce the burden of time-consuming in-person visits and expand patient access, especially in underrepresented patient groups or communities. If the DCT is deployed conscientiously, technology could help to drive a better site experience and help to minimise their operational workload, if not, the provided solution could increase site burden.

Trial decentralisation should be addressed as a great spectrum, with most DCTs combining in-person and remote activities as hybrid studies, to make clinical trial participation easier for patients and to find the balance between operational feasibility and the technological burden on sites and patients.

Below are the 15 top considerations for DCTs as determined by the ACDM eDigital Data Management Expert Group for data managers.

Top 15 considerations

- 1.** Define the data flow. In the same way you might consider having a patient flow chart, just as important, is the creation of a data flow chart to enable teams to understand how increasingly complex and disparate data will be collected, stored and analysed.
- 2.** Allow for interconnected systems. To reduce site burden and the likelihood of errors any interconnectivity between systems should support the study team seamlessly, where possible, e.g., a randomisation trigger in an eCOA device could integrate data to trigger randomisation within the IRT system allowing the site to complete a randomisation within just one system.
- 3.** How will you ingest, process and present the data? Depending on the protocol, you could be receiving data from ePRO, eCOA, eDiaries, wearables and/or sensors, Televisit and eConsent in addition to the more standard data such as lab data and you need a place to query and consolidate the information. This might be in your EDC or in another platform.
- 4.** Define your source of truth. Data consolidation makes it easier for users to analyse data, however it can create an issue of where the source of truth is if the data has been queried elsewhere.

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- 5.** What are the global and local regulatory updates? For example, you may have certain countries that do not accept eConsent, therefore it is important your DCT solution is flexible enough to account for the differing regulatory landscape.
- 6.** Define your DCT solution review team early. While it is important for our classic electronic systems to have a varied review team it becomes even more pivotal when implementing a DCT solution to include as many different stakeholders as possible with emphasis on individuals performing a full solution end to end review i.e., creating specific patient scenarios within the full DCT solution.
- 7.** What technology are the sites familiar with? Using the same technology used by the site can help them to feel more engaged with the study which can have a positive impact on their experience and on patient recruitment. It is important for sponsors to understand the trade-offs of the remote and hybrid format of DCTs, by balancing the technological burden and the variety of the different systems we use in clinical trials.
- 8.** Are there training requirements? If the technology is new to sites, patients or sponsors, training will need to be provided. The DCT solution could be well implemented but if the team are not confident using it – it could set up the study for failure. If training is required, train on the solution not the technology. Sites are not asking for lots of different systems. They need to be trained on the use of the set of technologies specific to the study. Instead of X training sessions for X technologies, ideally prepare a single training session for the end-to-end DCT solution. The best person to do this could be the data manager.
- 9.** Is an engagement strategy in place? This should aim to deliver the necessary level of engagement with the technology from the patients (and the sites) to help achieve the volume of data required to meet the study's primary and secondary endpoints.
- 10.** Have you completed a vendor analysis? Partners can turn a daunting new trial into a positive experience, if the selection process and communication throughout the project are managed well. You need to consider the vendor's level of experience developing these solutions and the features available in the platform and whether it is able to fully support the clinical trial (e.g., if you are using eConsent you might need an option for wet ink signatures as well as eSignatures depending on the country mix). When utilising multiple vendors to create a DCT solution it is also important to consider partners who have a strong previous working relationship to ensure a smoother process.
- 11.** Are the digital instruments (measures, questionnaires, diaries) validated for the use case intended? If not, does a plan exist to validate the instrument(s) as part of the execution of the trial?

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12. Does data protection meet GDPR and GCP standards as well as Data Governance? Data protection and storage is increasingly complex and there needs to be as much consideration for where the data will be located and kept securely for the required duration and what data, if any, can be reused and where this will be stored for ease of access. Data governance is also important and sponsors would need to have transparent processes in place to collect, integrate and analyse data strategically to advance their drug development programs and leverage data insights to improve trial design. Data traceability is a critical element in the process which provides full traceability of the data as it is processed and transformed within the systems and data collected from different source systems like wearables should be encrypted which should meet the standards to prevent any data loss or cyber security threats.

13. Has a Data Risk Assessment been completed? The use of the technology solution by the patient brings with it risk of data inaccuracy and gaps. A specific risk assessment is called for to consider all the potential scenarios that might occur and how this could impact the usability of data.

14. Has the data manager been given the time to contribute to DCT challenges and opportunities? A common area of concern amongst data managers is how early teams engage them when needing to accommodate certain aspects of DCT trials. There are many considerations to take into account to ensure data is managed correctly and data managers can be great advocates to ensure the overall success of the clinical trial.

15. How will you learn from your experience? DCTs or, more commonly, hybrid trials use a variety of different elements to help engage sites and patients and provide new data insights to clinical trials, most of which have been used for many years, however there is still much to learn and continuous innovation continues to offer yet more choice. It is critically important to take the time needed to come together as a team to share and learn from the experience.

The eDigital team would appreciate hearing from your own experience. Please do not hesitate reach out to the authors on LinkedIn or via admin@acdmglobal.org

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