The trial of the future: using digital technologies to enable decentralized trials

BY SUDHA SUNDARAM

Conducting a successful clinical trial is by no means an easy endeavor; it requires extensive planning to ensure that multiple resource- and time-intensive activities are completed seamlessly. In a post-Covid-19 world that is heavily reliant on virtual tools, the healthcare industry is leveraging digital health technologies to optimize clinical trials.

Gunnar Danielsson, Sr. Regulatory Advisor at LINK Medical

Clinical trial planning starts off with approving an optimized protocol and is soon followed by a host of steps that include pursuing and obtaining approvals from authorities; recruiting participants; procuring and administering treatments; collecting and analyzing data; and finally reporting.

"Today, all major tasks in clinical trial planning — barring one important exception — can theoretically be done digitally," said Gunnar Danielsson, Senior Regulatory Advisor at LINK Medical, a European early-stage development to post-market CRO.

This task is patient examination and assessment by a physician, which requires a clinic visit. However, this in-person task can be conducted digitally as well.

When almost all aspects of a trial are performed digitally, it is considered a decentralized trial. *"In a decentralized trial, activities like patient consent, assessment, and data collection are not conducted in a traditional setting such as clinics or hospitals. Instead, digital health technologies such as sensors, online patient-reported outcome surveys, or video assessments can be used," clarified Danielsson.*

The advantages of decentralized trials

Decentralized trials are aimed at reducing patient burden and optimizing trial operations. A recent McKinsey survey found that roughly 70% of all trial participants live more than two hours away from the trial site, which can make trial participation a burden.

"With decentralized trials, we can conduct clinical assessments where the patient is situated, for example in their homes, and at times suited to them. This can significantly reduce patient burden, positively impacting patient recruitment and retention in a study," said Jo Anders Rønneberg, Biometrics Director at LINK Medical.

Decentralized trials can reduce the required travel time, costs, and logistical arrangements, offering a practical option compared with on-site trials. This is especially relevant in the context of restrictions imposed by the Covid-19 pandemic.

Moreover, conducting decentralized trials digitally allows information to be exchanged and clarified rapidly between the patient and trial staff through multiple mediums, such as texts, presentations, emails, or video calls. Danielsson added that this typically increases data flow and enhances patient engagement in the studies.

By increasing patient convenience and involvement, decentralized trials allow access to a broader and more engaged patient population versus on-site trials, effectively eliminating time zone and geographical restrictions.

The benefits of this trial type also extend to the trial staff. In on-site trials, data is first documented in hospital records and then transferred to electronic databases. Decentralized trials have fewer data transfer steps, as the data gets directly captured in an electronic format at patients' homes. This reduces data collection and management arrangements, cutting staff workload and limiting the introduction of errors or discrepancies in the data.

Jo Anders Rønneberg, Biometrics Director at LINK Medical.

"By reducing the site involvement and resource use, decentralized trials not only result in time- and money-savings, but they also multiply the chances of finding sites ready to participate in a study," said Rønneberg.

Lastly, depending on the study requirement and the digital health technology involved, decentralized studies can also offer higher quality, real-time data, with potentially more extensive datasets compared with that from on-site trials. This can provide important context, enabling the examination of different trends and the application of risk-based approaches in downstream data analysis, ultimately improving the rigor of outcome reporting.

Defining where a decentralized trial is appropriate

The feasibility of a decentralized study is determined by the availability of a suitable digital health technology — which has been validated for verifiable and secure data collection and monitoring — within the therapy area in question.

For instance, an Apple watch collecting blood pressure data in real-time can enable a decentralized trial for a hypertension treatment. However, tumor size can only be measured via physical examination and diagnostic imaging tools. As no technological aid to replace the latter currently exists, such an assessment must be conducted in-person.

Decentralized trials are also more suited to simpler studies, where extensive assessments may not be needed. These include "studies that are based on subjective ideas, centered on patient perceptions captured using patient diaries or questionnaires," explained Danielsson. "An ideal contender would be neuroscience studies, where questionnaires can be filled by the patient at home instead of in a clinic waiting room."

Conversely, early-stage trials during the drug discovery and development process are not suited to the decentralized format. For example, in a phase II chemotherapy study, outcomes can be unpredictable due to adverse events or unknown effects. Considering the complexity in administering and monitoring treatments in such studies, the trials need to be conducted almost fully on-site.

"Defining where a decentralized trial is appropriate boils down to complexity, which can vary based on parameters like the indication, knowledge of the drug, trial phase, prior experience, and what sort of assessments can be done electronically," said Danielsson.

Challenges to overcome

Ensuring the availability of and access to a suitable digital health technology for all participants is a main challenge associated with decentralized trials. Participants should also be comfortable using the digital tools intrinsic to the study. This creates the need for patient training and support, which can be time and resource consuming.

"Regulatory requirements on data capture can also vary between countries, which can complicate the tailoring of data management to local requirements in a global decentralized study," added Rønneberg.

While these challenges may present significant hurdles today, such issues can soon be overcome with the increased use and evolution of the tools involved.

Looking to a decentralized future

"Although a majority of trial protocols may not be fully decentralized today, the tools to run decentralized trials are already widely in use," emphasized Rønneberg. Leading CROs like LINK Medical are well versed in employing tools like electronic data capture systems to integrate data from different sources; telemedicine platforms to interact with patients in real-time; and patient diary applications to track patient reported outcomes across trials.

Initial pilots have received an overwhelmingly positive response from patients, advocacy groups, regulatory agencies, health authorities, pharmaceutical industry, and CROs alike.

And this enthusiasm is likely to sustain, especially as the Covid-19 pandemic has accelerated the adoption of decentralized solutions. In a recent Global Data survey conducted with 150 healthcare stakeholders, 83% of respondents stated they believed that decentralized studies will be more frequently used in the next one to four years.

In therapy areas where a fully decentralized study may not be feasible, Danielsson suggested the use of hybrid trials as a viable alternative instead. *"In the short term, the way forward is to use the technology of decentralized visits in combination with on-site visits. This will enable advantages in times of resource saving and patient retention, without compromising on safety and efficacy assessments."*

Although decentralized trials may never fully replace on-site trials, "Decentralized trials will become increasingly common, as the healthcare industry starts to fully leverage the possibilities we have today," Danielsson concluded.

To learn how you can partner with LINK Medical and access the latest technologies to optimize your clinical trial, please visit www.linkmedical.eu.

Any questions? Contact the LINK Medical team or join them on the upcoming webinar on decentralized trials happening April 28. Learn more.

How clinical trials benefit from a decentralized solution: A Nordic case study