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How clinical trials benefit from decentralized solutions: A Nordic case study

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Digitization is changing the way clinical trials are conducted. Spurred by the pandemic, decentralized clinical trials are on the rise, with clear benefits for clinicians and patients. Three Nordic companies have teamed up to analyze the effect of decentralized solutions for a clinical trial on neuropathic pain.

With electronic devices available in most patient households and an increasing offering of dedicated decentralized solutions, many tasks in a clinical trial can now be performed digitally. Thanks to tools such as online questionnaires and video calls, clinicians and patients can stay in touch throughout the study, reducing the time for travel and on-site visits.

Märta Segerdahl, Chief Medical Officer at AlzeCure Pharma AB

In an ongoing pilot study, three Nordic companies are analyzing the effect of decentralized solutions in a clinical trial for a novel treatment for neuropathic pain. AlzeCure Pharma, a Swedish pharmaceutical research and development company, employed the services of LINK Medical, a Norwegian contract research organization, and Viedoc, a Swedish provider of decentralized software solutions for clinical trials.

"As a group of experienced clinical developers, we have probably seen most of the pitfalls that can happen during a clinical trial. Especially during the pandemic, companies had to change the strategy from on-site visits towards remote visits, reducing the burden on patients," said Märta Segerdahl, MD, Ph.D. and chief medical officer at AlzeCure Pharma AB. "And that worked surprisingly well. Patients appreciate that they don't have to frequently travel to a study site for hours."

Approved screening tools for efficient patient enrollment

In the enrollment phase of the pilot study, decentralized solutions using web-based questionnaires and phone or video interviews are applied to limit the number of patients coming to the clinic, filtering out those not meeting the recruitment criteria.

For instance, patients with neuropathic pain are very sensitive to touch or changes in temperature in the affected area. "We ask the patients what it feels like to have bedsheets touching their feet. That's one of the first questions a physician will ask to narrow down the diagnosis," Segerdahl added.

Decentralized eligibility screening tools that have been validated and approved by regulatory authorities are available for many common diseases.

"Everything we share with the patients has been officially approved by an ethics committee," Hedda Magnusson, director, Clinical Operations at LINK Medical Research, explained.

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Moving towards digital patient consent

Once a patient cohort has been identified, patients must officially consent to participate in the clinical trial. Viedoc's eConsent process includes videos explaining the study details, which are shared with the patients, along with the informed consent form (ICF).

"Patients appreciate that they have plenty of time to watch the video and read the ICF document in advance. If they decide to participate in the study, they will bring the signed document when they come in for their first physical examination," Segerdahl said.

Henrik Blombergsson, COO of Viedoc Technologies

While electronic signatures (eSignatures) are part of Viedoc's solutions, use and acceptance vary. "This is why we also offer hybrid options, down to the level of individual study sites and patients," explained Henrik Blombergsson, COO of Viedoc Technologies.

Reducing on-site visits and improving data quality

In the ongoing trial, on-site visits are required to monitor the treatment's therapeutic effect. However, patients can receive questionnaires to fill in from home, and the data are fed into the study database, where they are immediately visible to site staff, clinicians, and data monitors.

"When collecting the data on paper, it could take some time to discover if a patient misunderstood the questions. For example, when using a scale from 1 to 10 to describe the pain level where 1 is best and 10 is worst, the patient may think it's the other way around. With online questionnaires, we can identify misunderstandings quickly and get back to the patient for clarification," Magnusson said.

If patients have issues filling out the forms, the study site can offer help via phone or video calls. "Some say that the elderly — who make up the majority of the participants of clinical trials — cannot use electronic tools for data capture. But we see that many of them are really savvy, and even if they are not familiar with using a smartphone, they like to learn. They can also choose to fill in the questionnaires on paper," Segerdahl added.

Balancing on-site and remote activities for optimal results
Ideally, a combination of decentralized and on-site steps should be tailored to the particular clinical trial. In the case study, participants will be interviewed about potential adverse events during a follow-up visit at the end of the clinical trial. Based on patient preference, this can either be conducted remotely, via a dedicated Viedoc tool, or on-site.

"Additionally, if an adverse event occurs during the study, we can take action immediately because patients can contact us directly using their smartphone," Magnusson stressed.

The clinical trial of the future is decentralized

Moving forward, the use of decentralized solutions is likely to increase as the benefits become more widely known. Patients eligible for therapy but living far away from the study site will be able to participate, supported by local general practitioners serving as satellite study sites for physical examinations or blood draws. As a next step, analytic procedures could be optimized to use dried blood spots that patients can take at home with a simple finger prick and send to the study site by mail.

"I think it is the ultimate goal to do as much as you can remotely because decentralized solutions present a win-win-win situation for patients, clinicians, and study sites," concluded Blombergsson.

Contact LINK Medical to learn how your study can benefit from a decentralized approach, visit AlzeCure Pharma for more information about the pilot study, and see Viedoc's website for an overview of their full suite of eSolutions for clinical trials.

Images courtesy of LINK Medical.