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Real-World Experience Driving Continuous Improvement In Decentralized Clinical Trials

Asia Pacific continues to be an attractive location for clinical trials given the large population, diverse ethnicities, treatment naïve population and rapid growth of the pharmaceutical market. At the same time the region's consumers and industry leaders have always been recognized for their openness and acceptance of new technologies, therefore it seems likely that the shift to decentralized clinical trials will be smooth. However different the regulation, cultures and languages may be between Asia Pacific and the rest of the world, attracting, recruiting and retaining patients continue to be universal challenges. So how can sponsors, regardless of the location of the trial, ensure that they reap the recognized benefits of decentralized clinical trials, increasing patient recruitment, retention and compliance?

The deployment of decentralized clinical trials over the past few years has generated valuable real-world experience to drive continuous improvement in the virtual setting. Trial sponsors now have a clearer view of critical success factors such as early planning to ensure optimal engagement with patients and sites, selecting the right home-care services, wearables or sensors.

Getting the essentials right can be transformative, as illustrated by CHIEF-HF, a decentralized study of canagliflozin in heart failure. It achieved around 98% protocol compliance, using electronic patient-reported outcomes (ePRO) and eDiary technologies. Feedback from patients was highly encouraging. "Patients would recommend participation to friends and family, they found the devices easy to use and the reminders helpful," notes Kim Hedges, ICON's senior clinical program director.

Patient satisfaction is a significant driver of patient compliance in clinical trials. The CHIEF study emphasized the value of real-time support during the trial via virtual concierge services. These services helped with welcoming patients, managing consent, scheduling visits, responding to patient concerns, collecting reported events or retrieving equipment.

CUSTOMIZED TRAINING FOR SITES AND PATIENTS A CORNERSTONE FOR SUCCESS

Growing experience with decentralized trials has also highlighted some continuing challenges. One of these is the importance of site training. "Often there may be gaps between the site-initiation visit and other processes leading up to the first patient in. Some retraining may be needed to refresh sites on the responsibilities set out in trial documentation and accompanying materials." Comments Hedges.

Sponsors must also be careful not to lose sight of patients in the home setting. By increasing touchpoints with trial participants, sponsors can ensure patients are filling out their eDiarys or generating ePROs on a scheduled basis. With a central team monitoring these inputs digitally behind the scenes, sponsors can identify and address any compliance issues sooner rather than later.

Early training of patients is part of the sponsor's roadmap for success in decentralized trials. "We actually have a team that runs through that end-to-end experience, for sites and patients," Hedges points out. "If we're going to give patients an application and connected devices to use, we want to make sure that's a positive experience for them."

Trial apps incorporating documentation and videos facilitate onboarding, so that patients have a reference point to help keep them on track. "If we've done our job right, they can use the application, go through their eDiary and ePRO, with minimal disruption to their normal daily schedule" Hedges comments.

Sponsors may also face varying degrees of participant familiarity with digital devices and media. "We can't assume that all sites and patients have the same level of comfort with decentralized processes," Hedges comments. "Even participants with experience of smartphones or apps may struggle during a trial if they are dealing with other issues in the home setting."

DEVICE AND SERVICE OPTIONS

Selecting the right devices for a decentralized trial is also far from straightforward. The sheer range of possibilities "can be overwhelming", Hedges acknowledges. ICON has a team dedicated to ensuring, for example, that selected devices tick boxes such as operational excellence, safety and patient engagement. Study objectives will feed into these considerations.

Device selection also depends on the therapeutic area involved, study duration, endpoints, patient-burden assessments, whether the trial is blinded or not, and whether it involves passive monitoring or active assessment. Patient-centricity and device useability are paramount, as are device characteristics such as battery life and connectivity. Sponsors also need to think about device validation, data transfer, storage and visualization, and regulatory issues such as privacy and security.

"We go through a pretty rigorous process of vetting the devices," Hedges says. That includes considering what type of device best suits the patient's daily routine: whether they wear a watch or armband, for example; or whether the device and any associated apps include remote capability for data transmission. ICON uses patient and clinician user groups to test out the practicalities of new wearables or other devices. That might be something as simple, yet key to compliance, as how easy it is to place a blood pressure cuff correctly to capture and transmit accurate readings on the device.

Selection of other virtual care options, such as in-home nurse services, is also closely managed. For each trial, a dedicated team at ICON, traces the whole patient journey through the trial and makes recommendations on service elements, based on therapeutic expertise and parameters such as study outcomes.

It is crucial that the whole infrastructure to support patients and sites is in place before decentralized trials go live and that this is maintained throughout the trial.

Reducing the administrative burden on sites, such as determining whether patients want to participate and explaining how the trial works, is another important driver for early planning and action. Once the study is up and running, the sheer volume of data points can be another challenge for sites. Using a dashboard enables sites to sift out "the data they need", Hedges says. "It doesn't take a phone call to gather and assess that information, because the information is displayed right in front of them."

DEFINING ROLES AND COMMUNICATION CHANNELS TO BUILD STAKEHOLDER CONFIDENCE

Defining and clarifying roles and responsibilities clearly in advance gives sites and physicians confidence that the team has experience in overseeing patients virtually, and that any issues arising from interactions between, for example, patients and concierge services, will be escalated and conveyed promptly to sites.

Seamless connectivity and communications between study teams and sites help to keep decentralized clinical trials moving forward on time and target. ICON uses a number of established mechanisms, such as shared sites or integrated systems, to enhance interaction between teams and sites, as well as looking to newer technologies like chatbots. Messages can be exchanged between the trial platform and dashboard, or with trial patients through the same channel.

CLOSER TO THE POINT OF CARE

Once physicians understand that the technology driving decentralized trials is complementary, and not about increasing burden or affecting their relationship with the patient, they are more comfortable managing patients outside traditional brick-and-mortar settings.

By streamlining interactions with, and enhancing confidence and trust in, health care systems through enhanced information flow and patient-centric strategies, decentralized trials can also improve patient engagement with care processes as they shift responsibility to self-management of conditions in the home.

This is especially pertinent as sponsors seek to replicate real-world conditions in technology-enabled studies. "We know that, ultimately, the majority of patients want to be outside the clinic and hospital setting," Hedges says. "They want to be at home. That is where they manage chronic diseases, and have done for years."

In that sense, decentralized clinical trials conducted remotely can actually bring patients closer to the point of care. As Hedges points out: "The more we can align with what feels more natural for a patient, which is being at home and taking care of as many of their health issues as possible at home, with the right support, that is a win-win for patients as well as trial sites and sponsors."