How Decentralised and Hybrid Clinical Trials can Support Subject Recruitment and Retention to Support Clinical Trial Success

Decentralised and hybrid clinical trials are delivering benefits for sponsors in a number of ways – delivering quality data quicker to reduce time to market, achieving higher levels of compliance, increased diversity of patients participating in trials, and importantly, recruiting and retaining more subjects.

Encouragingly, there has been significant progress in decentralised and hybrid clinical trials in the last few years, with the global COVID-19 pandemic serving as a catalyst that brought major shifts in how we approach the execution of clinical trials. Although the recent uptake has been considerable, decentralised clinical trial components have been successfully implemented and ongoing for quite some time, and we have seen different phases and scales of adoption across the board. More organisations are rolling out pilot programs, implementing hybrid trials more extensively and overall delving deeper into decentralisation to explore the benefits it offers.

Therefore, at this point in the shift to decentralised and hybrid studies, we are getting valuable real-world experience that enables us to drive continuous improvement. Sponsors now have a clearer view of critical success factors such as early planning to ensure optimal engagement with subjects and sites, selecting the right in-home clinical services, wearables or sensors, and staying close to the patient throughout the study.

I'll explore these lessons in this article, in addition to outlining some of the key elements that need to be in place in a DCT setting to ensure good levels of patient retention.

Enhanced Convenience Drives Enhanced Recruitment

In any clinical trial, be it decentralised or not, the priority is always the patient. We conducted patient voice surveys in 2019 and again in 2020 to better understand attitudes toward decentralised or hybrid trials. The findings indicate that patients are open to decentralised clinical trial approaches, and overall, they want the options and flexibility they provide.

Decentralised and hybrid clinical trials overcome two common hurdles for recruitment and retention: accessibility and convenience. Typically, subjects that participate in clinical trials live within 50 miles of the site. In our most recent survey in 2021, 90% of respondents were not willing to travel more than one hour to participate in a clinical trial. The physical parameters and burden of travel associated with traditional trials exclude significant populations of patients that are either incapable or unwilling to travel to the site. Providing hybrid and fully decentralised clinical trial options eases the burden of travel and delivers a more positive and convenient patient experience.

Furthermore, the removal of geographic constraints unlocks the potential to recruit participants from more locations, and from more diverse backgrounds. Increasing the diversity of subjects that are participating in clinical research is an important goal we are all working towards in the industry. Our experience of designing and conducting decentralised and hybrid trials to date certainly indicates that by increasing the number of patients we reach, we also achieve increased diversity.

Reducing Patient Burden Through Consistent Support

Reducing patient burden is perhaps even more important in a DCT setting as the flexibility of decentralised methods and technology can potentially replace one challenge with another, for example, using the technology devices themselves.

So, how to approach this? Using the right technology devices and maintaining sight of patients throughout the trial are critical elements.

Selecting the right digital health technology devices is paramount. The sheer range of possibilities can make this challenging. Fundamentally, selected devices must tick boxes such as operational excellence, safety, storage and visualisation, and privacy and security. 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. And just as important are patient centricity and device useability. Consideration must be given to participants' levels of technology familiarity and comfort. The more comfortable they are in using the selected devices, the more likely they will remain in the trial.

Maintaining sight of subjects in the home setting is also hugely important from a retention perspective. By increasing touchpoints with trial participants, sponsors can make sure patients are filling out their eDiaries or generating ePROs, for example, on a scheduled basis. And so, while it may seem obvious to state, staying close to and supporting the patient is an absolute must.

Dedicated concierge services are important to ensure patient support is fully embedded in decentralised or hybrid trials. The expertise to fully support patients in setting up connectivity to digital platforms, devices and wearables should be considered where digital health technologies are included in the clinical trial. And while assisting patients with technical support is essential, ensuring retention requires engagement beyond technical support.

Direct inbound and outbound communication with patients improves overall engagement, compliance and retention throughout the trial by onboarding the patient and being a central contact for any challenges they might come up against. Customised patient programs ensure the support is aligned to the patient profile and challenges, expected in the disease or indication.

How does this patient support look throughout the clinical trial? This is best outlined by looking at the patient journey.

One of the ways these services might start the support journey during a trial is by reaching out to a patient, after screening, to schedule visits – telehealth, site visit or

a combination. This support will include the downloading of digital study apps (eDiaries, ePROs, etc) if they are using their own mobile devices.

If a mobile device is sent to the patient, once they receive their device, an outbound call welcoming the patient into the study will be placed, walking them through logging into the digital study app, setting up, and making sure the patient understands how to use the technology and ensure information is being transmitted correctly. At this time, the coordinator will review study instructions with the patient, Investigational Product delivery and go over dosage instructions.

When the patient has everything that they need to begin their study, the service shifts into a monitoring and oversight phase. For example, if a study requires patients to do daily eDiaries on their medication adherence, the coordinator will review the entire study population and perform outreach to those who have missed their eDiary entries and assist them with any issues that have arisen.

In this monitoring and oversight phase, anomalies in reporting can also be identified. The patient coordinator will track deviations in timeframes or missing data – and when the data goes back to the informatics team, they are able to review the anomalies. This real-time monitoring of progress means that issues are dealt it when they happen rather than affecting data quality and compliance when it comes to close out.

As the patient gets to the end of the study, the patient coordinator will provide instructions on the return of any equipment, medication destruction, generally ensuring that the logistics behind closing the study are all dealt with efficiently.

Overall, the concierge support service informs patients what they should be doing, reminds them when they need to do it and assists them along the way. The coordinator is the patient's central point of contact to help support them and ensure the patient-physician relationship is really focusing where it should be, on the treatment and care, and less on the day to day demands of the study. This all supports the objective of removing the burden from the patient, ultimately supporting increased retention.

The benefits that can be delivered through decentralised and hybrid clinical trials are compelling for sponsors. Incorporating these approaches into clinical research opens the possibility for reduced timelines and cost savings while increasing the accuracy of safety and efficacy evaluations of investigational medical products. Of course, before these benefits can be realised patients need to be recruited and remain in the trial until its conclusion, which is another area where decentralised and hybrid trails are delivering for sponsors also.

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Laney Preheim, Vice President of Concierge Services at ICON, has over 20 years in the high-tech industry, with the majority of her career focused on the unique intersection between healthcare and technology. She leads the global Concierge Services team at ICON, which includes offerings such as direct to patient services, site support, device logistics and patient safety surveillance and reporting. Laney's team drives services that deeply consider and improve the patient journey and site staff study experiences, across the clinical trial process. She joined ICON in 2021 through the acquisition of PRA Health Sciences. Prior to this, Laney was a key member in the formation of the executive leadership team at Care Innovations, a unique remote monitoring start-up. She previously held a variety of positions at Intel Corporation in the Digital Health and Information Technology organisations, with focus on procurement, ecosystem enablement, product management and strategic planning where she has been at the forefront of managing organisational operations for the development of innovative strategies. She earned a Bachelor of Business Administration degree from the University of California, Davis.