Supporting Investigators and Sites in the Evolution to Decentralised Clinical Trials

The growing uptake of decentralised clinical trials in recent years reflects several key drivers such as advances in remote monitoring technology and data analytics, the need to access broader, more diverse trial populations, and demand in clinical development for cost efficiencies and more meaningful, real-world study outcomes.

However, we are at a point that if this approach is really to be considered business as usual, it needs to have acceptance by and support from all stakeholders, including investigators and site staff.

Historically, the physical interface between sites and study participants was the primary connection in clinical trials. While decentralised clinical trials may ease patient burden and potentially some administrative burden on sites, they can also raise concerns about loss of direct patient contact and revenue generation.

It is therefore critical that sponsors communicate effectively with their sites about how associated services, such as in-home services, will work to the advantage of not just the patient but the investigators and site staff also. Sponsors should also ensure they provide the right support and appropriate training to ensure that these advantages are recognised and exploited at site level.

A few years ago, ICON conducted a survey to get a pulse check on site sentiment and their experiences during the COVID-19 pandemic, when decentralisation really took off. At that time, the survey found that nearly 70% of site staff had little or no experience of remote processes before the pandemic. Nonetheless, more than 78% of staff felt remote processes were to their benefit, while over 90% were expecting to see more decentralisation. It showed that there is an understanding and an acceptance that decentralisation of clinical trials is here to stay and will only grow.

The varying levels of experience and capability that sites have in managing decentralisation depends to some extent on the health care system they operate within. Across the board, exposure to related processes and technologies increased under pandemic conditions, but exposure and being equipped with the skills to use such decentralised technologies are two different things. The onus is firmly on sponsors and their partners to ensure that sites still feel comfortable with the changes and bring them on the journey.

Shifting Administrative Burden and Workload from the Site

One potential benefit of decentralised clinical trials is a reduction in administrative workload for trial sites. For example, recruitment presents a significant workload challenge for investigators as well as trial sponsors. Digital patient recruitment strategies can reduce burden from sites and support reduction of overall timelines.

As patient assessments are increasingly conducted through digital health technologies capable of primary data capture, less time is needed to interact with clinical research associates (CRAs) on clinical monitoring. In a decentralised clinical trial setting, much of this activity is automated and digitalised.

However, all these changes represent a shift in the well-established operational and business model for the site. Inevitably, these changes present new challenges for investigators and sites, such as familiarising themselves with new technology and managing the new elements of a decentralised clinical trial and, it may not necessarily feel like it's less workload initially. This is where sponsors need to go the extra mile and look to provide a range of interventions to help sites manage the decentralised model.

One suggested tactic is arranging consultations with sites at the start of the trial, so the sites know exactly what to expect from decentralised study designs. It is also important that sites can form a comfortable relationship with service vendors in this context.

Moreover, ensuring the site understands the whole patient journey within the framework of trial delivery, especially the site's role in facilitating that journey is vital. Additional support services, whether they address recruitment, reimbursement, or logistics, can help clarify these areas while ensuring that the administrative burden of the trial is truly removed from the site as well as the patient.

Building Confidence in the Model

Decentralising a clinical trial involves innovative approaches and the sheer range of technologies now available from multiple vendors and multiple platforms can also be intimidating.

Investigators and sites not only need to understand how these technologies work, but they must also be confident they will work well, without complications such as data loss or incompatibility with data privacy regulations. Sites also want to avoid being burdened with having to provide a technology support service to patients. A busy site coordinator doesn't want to have to start showing patients how to log on to a system or how to correct their e-diary.

Moreover, sites need reassurance that vendors such as home-health nurses are properly qualified, trained, and compliant with Good Clinical Practice (GCP) and International Conference on Harmonisation (ICH) regulations. Site staff can help to address these concerns by providing feedback on their experiences to inform continuous improvement of decentralised processes.

There are also some key relationship changes to take on board. With traditional clinical trials, the main interaction is with investigator site and patient. That changes with a fully decentralised trial, where it may be a concierge support service engaging regularly patients to support them through the clinical trial journey, making sure assessments or patient surveys are completed correctly and on time, hence assuring patient compliance.

At the same time, the trial site remains responsible for medical oversight of participating patients, whether visits are site- or home-based. Although the site's relationship with the patient is going to be different, it is important that sites do not feel they are losing touch with patients and are reassured that trial participants will be carefully looked after and supported. For their part, patients must understand, through the trial consent process, who will guide them through the trial, and that any concerns must still be taken to the investigator responsible for medical oversight.

Direct to Patient Support Services

Sponsors should seriously consider building in concierge services to support both the site and the patient. These services will need to be customised and will vary according to the characteristics of the study and the patient schedule of visits, and then integrated into the clinical trial process seamlessly so that it effectively lightens the administrative burden on trial sites. Concierge services that can provide both technical and clinical support can help with access to portals, apps and wearables and sensors but also support the drug accountability process when direct to patient shipments are used. These services are provided efficiently and remotely, and ultimately reduce unnecessary calls to sites staff. However, these professionals are also trained to triage calls and ensure the site is made aware of any medical issues to maintain the necessary medical oversight.

Additionally, sites are encouraged to build relationships with in-home health professionals, so they can be confident their activities (such as drug administration, taking blood samples, questionnaires, and clinical assessments for vital signs) are in line with protocols while prioritising patient convenience and safety.

Decentralised Trials are a Long-term Reality

If investigators and sites are partnered, supported, trained in the right way, the benefits should be felt all round: faster, broader, more diverse patient recruitment; more seamless, integrated data exchange; improved granularity and real-world significance of the data collected; and reduced administrative burdens on sites.

Without the unnecessary distraction of time-consuming activities that can be automated, digitalised, and potentially managed remotely, sites can continue to pursue their research interests and care for patient needs, without diverging from the common goal of delivering timely and effective treatments.

Harpreet Gill

Harpreet Gill has over 20 years of experience in clinical research. She currently leads the global project management team in the delivery of Real World Solutions to pharma, biotech and medical device organisations. Prior to this she was responsible for driving strategy and operational delivery for decentralised clinical trials, accelerating clinical trial timelines and bringing treatments to patients faster. Harpreet previously held a number of roles with increasing responsibility at IQVIA. Most recently, she led the European real world evidence project management team with responsibility for P&L and client management. She also led the global epidemiology team for some time while supporting data management, biostatistics and HEOR to align business practice and embed rigour in business review processes and project oversight. When Harpreet joined IQVIA in 2001 she successfully set-up and developed the project management office, focusing on bringing best practice project management, skills training and systems process improvement to clinical trials teams and more broadly across the organisation. Harpreet is a Chemistry graduate with a BSc(hons) from the University of North London.