Trials and Tribulations: How Decentralisation Is Evolving

Tim Rich, Vice President, Digital and Decentralized Solutions, PPD Clinical Research Services, Thermo Fisher Scientific, talks us through the latest developments in the clinical trial sphere, and the new trial models to keep an eye on

ICT: **How have decentralised trials developed in the last decade?**

Tim Rich: For the origins of decentralisation in healthcare we could go back to when doctors first did home visits. However, as the healthcare industry has evolved over the years, the research space has followed suit. An example of the transition to research is telemedicine. At the same time, decentralised trials (DCT) have evolved from basic remote sampling to 100% of the data being collected in the comfort of the patient's home. We are achieving this through new technology capabilities, new remote workforces, and/or evolved site models that utilise community facilities and are used to operate in a fully virtual manner.

With this more patient-centric approach, our hope is that we are able to make research more appealing to patients as part of their treatment option.

What trends do you see in clinical trial design?

Healthcare is constantly changing, so we have to be diligent to make sure research maintains its focus on providing quality data and adapts to take advantage of innovation. Some examples of such innovation are basket trials, adaptive designs and dynamic protocol design – where the principal investigator and patient are ultimately given the option to use DCTs or a clinic within the approved protocol.

How has the alleviation of pandemic restrictions affected trial design?

We are all striving to find the bright spots from the pandemic. DCTs are one of the highlights. As the general restrictions and quarantines have been loosened around the globe, we are seeing that patients have more freedom to travel but the good news is that this is not resulting in us returning to pre-pandemic practices. We are still designing and executing DCT strategies because the realisation that we can do things differently is being recognised by all. We are also

in an environment that research has not been in before. Because of our important role in developing treatments and vaccines, we are central in the public's thoughts and there is much more awareness of our industry. We have an opportunity to capitalise on this point in history with information sharing but also ensuring patient participation is as easy as possible.

How can decentralised trial models benefit from more integrated technology?

Electronic health records, to connected devices, to electronic data collection enable us to push and pull data across the healthcare/research spectrum. These single end-to-end connected data processes where the patient, but importantly the site as well, do not need to complete administrative tasks that technology can perform is the ultimate when coupled with the ability to assess matching patients to specific trials.

Decentralised trials are our avenue to connect the practicality of design with this end-to-end integrated solution for data, but also to underpin the operational execution of DCT trials, across all roles. For example, the same DCT platform that matches the screening criteria of a patient and then pulls medical history data from electronic health records, is the same platform that a patient uses to enter their own data. The site can use this platform as eSource but also the travelling nurse, the lab, the radiology department – the list goes on. And as DCTs grows it will also grow in variability as well as volume.

This end-to-end integrated technology solution is great for in-study management but also gives us new avenues for patient identification and facilitating data collection from non-trial sources.

What more can be done by clinical teams to unlock even greater advantages in DCTs?

We need to keep patients central to everything we do and with that keep challenging ourselves on how we can make trials more appealing and make participation easier. If we keep that central, and we keep pushing boundaries of decentralisation, I think we can make research a credible treatment option for patients. To that end, clinical teams need to continue the trend of embracing change and the associated change management throughout their organisations, all of which starts with protocol design and building in DCT strategies from the first draft. When we have worked with clients to do this, we have seen the most success when compared to retro fitting DCT solutions into an already designed protocol.

How do you see clinical trials operating in the future? (Virtual trials, even more of a trend towards decentralised, things moving back on-site?)

I'd suggest that to some degree DCTs are applicable to most, if not all, trials and it is a question of where on the DCT spectrum they are positioned. I see continued growth in trials being performed in a fully decentralised/virtual manner whether that is through technology, virtual investigators or enabling the access of community facilities. So many of the challenges we face in research can and are being addressed by DCTs. For instance, it helps expand geographical reach of patients to recruit into a trial, it helps increase awareness of trials and it supports us facilitating more diversity into trials. It also helps with capacity management for sites where they can perform non-IMP administration visits remotely whilst continuing administration visits in clinic. From a patient's perspective, we are making participation easier and consuming less of their time. A recent survey showed that one-third of the time a patient devotes to a trial was spent travelling or sitting in waiting rooms, which is one challenge DCTs are addressing.

Building on this, I see trial design becoming more dynamic in nature with patient choice at the core, as DCT becomes more mainstream. For example, I'd like to see us get to the place where it is common practice for one patient to select attendance in person at the clinic for their visits whilst another chooses to join their visits remotely within the same regulatory approved protocol.

We currently see a disparity across the globe in terms of acceptance and execution of DCT strategies, as well as continued growth in all DCT solutions. Looking to the future, I would like to see a levelling of consistency across all regions around the world.

Tim Rich, Vice President, Digital and Decentralised Solutions, **PPD Clinical Research Services, Thermo Fisher Scientific**, heads the consultancy, innovation and strategy team, which is responsible for driving the growth of decentralised adoption while bringing forward integrated innovative solutions. Tim also leads enterprise-wide strategic decentralised growth plans in support of corporate objectives.

Previously, he was a member of the biotech solutions operational leadership group. In that role, he provided strategic direction, leadership and management across multiple divisions and therapeutic areas by utilising his 20 years of project delivery experience.

Tim's background also spans all elements of global project management, portfolio management, development operations, corporate development and strategy, and client relationship roles.