The Source and the Story – How Digital Transformation Truly Centres Patients

From data management to analysis and visualisation, clinical trials and their digital evolution has seen changes to plenty of aspects. Every patient's data are integral to the continued development and decentralisation of clinical trials

Temitope Keyes at encapsia

To run decentralised clinical trials (DCTs), clinical teams ideally need a singular, holistic platform that encompasses the collection, review, management, analysis, and visualisation of the trial data, however disparate that may be, utilising a single build process. This ensures consistency across the data sources as well as efficient management of any protocol changes.

When patients and sites are decentralised, you have numerous other data that may be coming from ambulatory imaging, phlebotomy, wearables, or in-home patient monitoring devices. It is crucial to have a holistic and real-time view of all the data in that trial, with visibility of trends across patients, sites, and possibly trials.

Your Patients Are Your Source Data

Even in traditional trials, when you send patients out the door with instructions on what the clinical trial is about, what their responsibilities are, what they need to provide back to the site, you will always have concerns about patient compliance regarding accurate and timely collection of the data. In DCT, tools like eSource/direct data capture (DDC), patient monitoring devices, electronic patient-reported outcome (ePRO)/electronic clinical outcome assessment (eCOA), and telehealth, are options that must be considered at the time of protocol design. For a successful study conduct, priority has to be given to making participation more convenient for patients, and ensuring that the trial is not disruptive to their lives.

Digital Strategy

Having a digital strategy for data integration before the protocol is even rolled out to the research sites is clearly identified as a key component of that success. Done right, it reduces administrative burden on the research sites and the clinics in collecting data and managing patients, thus speeding up site payment, and enhancing their satisfaction. Nevertheless, even if having that digital strategy in place reduces time on their end, there will still be a learning curve for sites. Sponsors must be forward thinking in planning and implementing these tools.

In the long run, it will definitely reduce labour and burden on the site side, and only further complement the relationship between the research site and the patient as well. In an industry (some would say) beset by acronyms and 'buzz' terms, what does patient centricity truly mean? It means facing this reality: "your data point walks out the door" if you don't have trial designs and tools that make it easy for them.

Patient Education

Patient education is a major driver of success. They need to understand what the monitoring device in their home does, how the trial will benefit them as well as patients like them, and how their participation is making an important contribution to the advancement of new treatments.

Two key questions arise when considering DCTs, data flows, patient participation and engagement:

1. What does it take to recruit, retain, and engage with patients while remote?

We can no longer afford to let postal/zip codes impede patient participation and access to innovative treatments and opportunities. This is why expanding the universe of potential sites, and taking advantage of technology to make non-traditional site participation easy, should be given weight when selecting vendors and tools.

Consider what data you are collecting with what tools you are using – how much data do you want to collect and how difficult do you need it to be? How will the chosen technologies improve the patient experience such that they want to be active participants? If we are truly centring the patient, then non-intrusiveness, ease of use, and ensuring that the selected tools and technologies provide a consumer-grade user experience, should be key criteria. Whether on a tablet, website, or in-home device, thought should be given to how they allow the site to remain connected to the patient but without becoming onerous or 'one more thing' to manage.

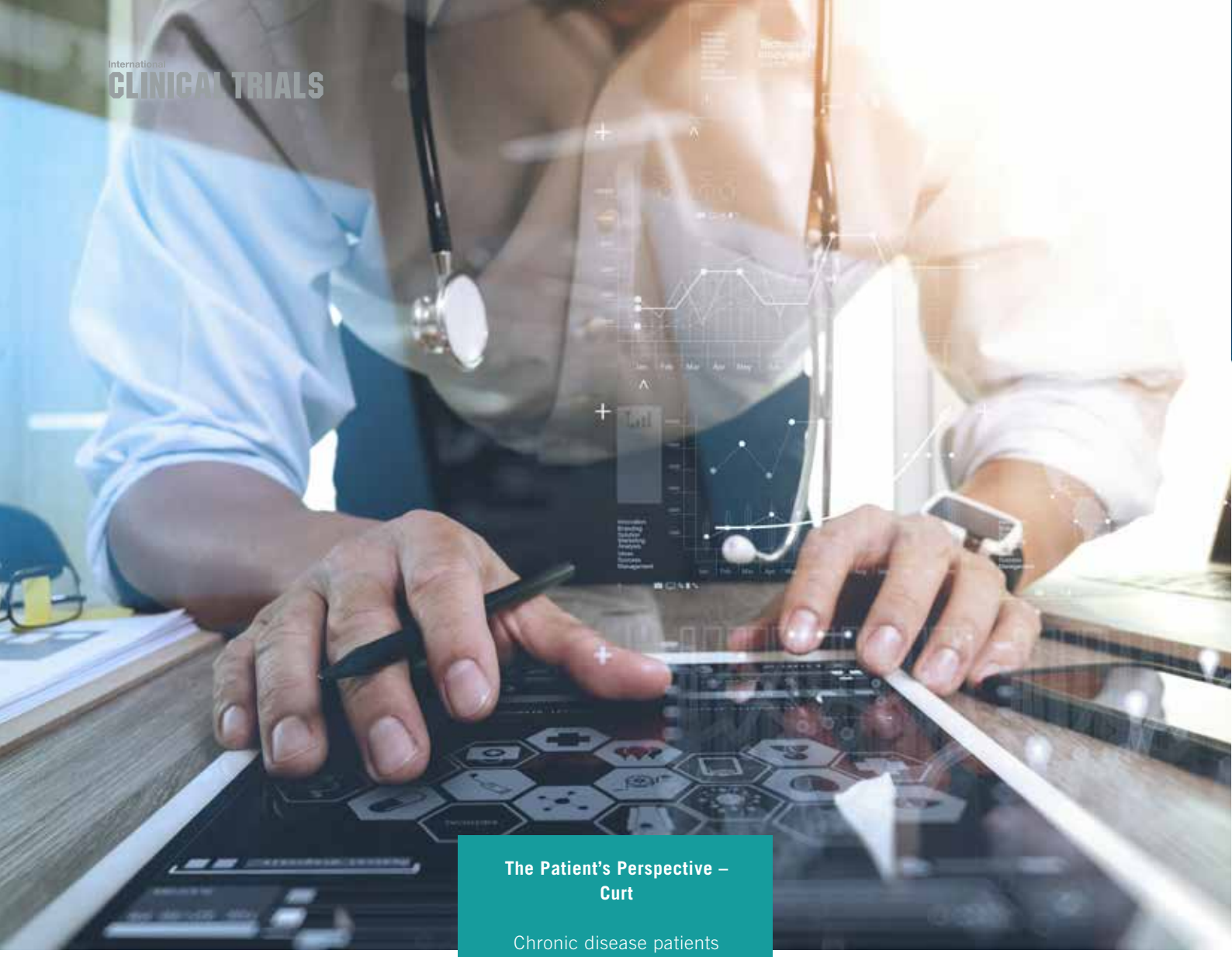
Reducing the number of total systems, tools sites, and patient use, will only ameliorate the challenges that come from running DCTs, because extra technology will never replace the valuable relationship between site and patient.

A Senior Director of Clinical Operations – mHealth provider discussed the impact of DCT on patients: "If I put my patient recruitment hat on, as a patient coordinator, I have had many early mornings 5-6am, or late evenings 5-6pm, even Saturdays and Sundays that I have had to work to keep a patient in the trial, to respect their life and what they had ongoing and also respect the part of being a volunteer for a clinical study – to keep them engaged, involved and all of the data coming in." They continued: "It also opens up the ability for patients who couldn't otherwise participate in a trial. There are people I talked to that were absolutely qualified, extremely engaged, and motivated, but because of the number of visits that they had to physically come into the office for, they just weren't able. And at age range 18-34, there were mothers with young kids who just couldn't be flexible with their schedules. So, in utilising and engaging DCTs, that really changes this for a lot of potential patients."

2. Why are we collecting all this data when only a subset of data is pertinent to the submission?

Minimising the data collected must be given consideration. Data management and biostatistics departments should be engaged in thinking about the study data needs strategically – what data are needed and whom should it go to, how do they need to be formatted and structured, and when are they needed? For sponsors and CROs, the key is to involve their partners in their data strategy to determine the tools they need, specific to their protocol, patient population, and clinical development plans.

Automation of data collection, aggregation, and integration will accelerate data cleaning, reconciliation, and completion. Some thought should be given to how your



data strategy may affect the statistical powering of the trial, e.g., faster data analyses may reveal insights supporting efficacy targets, thus reducing the need to open more sites.

No Going Back

We are at a point where we are not going back to old ways of study conduct, and when empowering patients to take more of a part in the process is the only way we deliver on the industry-wide promise to advance the health of our patients.

At the end of the day, the purpose of our work is the patient. We are providers of data, and of services, but those data are tied back to a real person who is living with a condition, and it is important that we always consider their perspective in our clinical development approaches, whether in the clinic or at their home.

The Patient's Perspective – Curt

Chronic disease patients have unique needs and DCT offers an opportunity for them to participate in clinical trials safely and access new therapies. I talked to one such patient on his experience in a clinical trial in the midst of the pandemic for his advanced stage neurological condition:

"It went well, other than having to take time off of work every month, and that wasn't that big a deal," said Curt. "It was double blind so I'm not sure if I actually got the drug, but I do feel slightly better. I am full of information about my own issues, but what I know just scratches the surface. I am sure each person has a different story to tell. I have learned that most doctors react to what patients tell them."

Temitope (Tope) Keyes has 22 years of clinical R&D experience, which began on the sponsor side, with the majority of that primarily in the eClinical solutions space. She has a passion for technology and its ability to advance vital clinical research and successful trial execution. Her experience includes pre-clinical purchasing and clinical outsourcing roles at AstraZeneca and Sanofi, followed by almost 15 years in business development with the likes of ERT, Synteract, Datatrak, and Axiom Real-Time Metrics. Tope joined **encapsia** in 2020, where she drives the sales and marketing for the encapsia clinical technology platform.