



Tech on Trial

While the industry remains steadfast in its old ways, new technology now exists that can revolutionise and streamline data and trial processes. *IPT* asks Cmed Group's David Connelly how

***IPT*: How is technology being implemented by CROs into clinical trials?**

David Connelly: Most CROs recognise that to succeed in today's world they need to embrace technologies, and successful adoption opens up many benefits and efficiencies. However, the challenge for CROs is that the industry is mainly characterised as having a patchwork of often dated systems that have inadequate interoperability. The implementation of new technologies takes time and resources, with the added challenge of managing clients and maintaining delivery during this transition.

What new and adaptable functionalities can these bring to CRO management?

New technology that can help and support the entire clinical trial team will benefit CRO management. For example, unifying all the data collection and management into one clinical trial data repository would allow better visibility of the data, guaranteeing more effective study management. Whether it be speed of conduct, quality,

compliance management, risk, etc, if you improve it, you make the job of CRO management more easy.

What different methodologies are used when capturing data?

A decade or two ago, 90% of clinical data was typically captured in paper form. Today, we use electronic data capture, eDiaries and the like, yet the data collected in the clinic are often recorded on paper first and then transcribed. Most data now comes from other sources such as routine labs, biomarkers, images, electrocardiograms and even wearable sensors. The difficulty is there is often a lag before all of this data can be consolidated and made available for review and analysis. Hence, the industry is now seeing a greater use of direct data capture (eSource) tablets at sites, new generation clinical data platforms that allow data from all sources to be held in one repository, giving live insights and analytics on the consolidated data. In the future, clinical trials will see more automation and application of artificial intelligence.

Does technology transform the patient/clinician interaction? If so, how?

The interaction between the subject and the clinician/medical staff is vital. Technologies should aim to enhance and not hinder this interaction. eConsent can help the site staff provide information about the study to subjects that is interactive and easier to understand. Social media can help raise awareness of a clinical trial and attract potential subjects

to participate in the study. Patient engagement tools (eg apps and text messaging that reminds subjects to take medication or attend a clinic visit) can help with compliance and encourage completion. eDiaries and wearable sensors can provide clinicians with valuable information about their subjects between clinic visits while multimedia can facilitate 'virtual' visits or consultations without the subject having to travel and attend the clinic. Technology is changing this interaction, but we have not yet fundamentally transformed it, and how much we should is questionable.

How do processes become more streamlined when one employs technology within their CRO?

The industry has many inefficient processes characterised by duplication of responsibilities and activities, as well as several manual steps and procedures. Technologies can fundamentally transform this. For example, if all the clinical trial data are collected and held in a single repository in the first place, much of the importing, exporting, mapping, integrations, etc are no longer needed. If data are captured as eSource or if technology enables a source to be viewed remotely, then a clinical research associate may not need to visit the site so frequently. Technologies help focus attention on the data that are most significant. Live insights and analysis of the data can highlight necessary actions and aid more timely decisions.

Keywords

CROs
eClinical technologies
mHealth

Are there any specific benefits for trial start-ups?

Starting up studies quickly and efficiently can be challenging. Usually these processes tend to be tracked by clinical trial management systems, though some software systems are particularly focused on assisting the start-up process. These can help with tracking status, visibility and highlighting issues sooner. They may be particularly beneficial for large multicentre studies. Another example of helpful technology is the use of digital signature software. Finding the right investigators can also pose problems, and many first time investigators are well-known to say they will never participate in another study. Making life easier for the investigator and site staff is very important and can be overlooked. While technology can help, the solution may be to focus on simplifying, harmonising and bringing about wider changes in the regulations and practices currently needed to start up a clinical trial.

Two key factors that often require a lot of attention are recruitment and adherence. How can technology within clinical trials help in these areas?

Social media can help recruit patients, and eConsent can make the patients' choice easier to participate. If patients are better informed and understand the study, they are also more likely to adhere to the protocol and be compliant. Patient engagement tools can help remind and prompt subjects. Another key area is subject safety. If data are collected live – or as close to live as possible – and are available for immediate review, patients can be monitored

closely, thus keeping them safer and allowing researchers to intervene if any issues arise. It also enables more accurate admission of subjects against the eligibility criteria of the study.

What improvements have you already witnessed in the last five years?

The industry is generally a late adopter of new technology and has made disappointing progress in the last five years. The pharma sector is characterised by using relatively dated technologies that have poor interoperability and then adding new tools and technologies on top that address one need, but often create further problems and more cost. The industry has been slow to apply the modern technologies that are available to the consumer, often playing safe and finding it more comfortable to keep piloting instead. Progress is being made in some quarters, but many pharma companies and CROs could be bolder, more decisive and look at what could be achieved if they started adopting newer technologies now.

Where do you see new technologies taking clinical trial data in the next decade?

Modern technology that transforms everyday lives like smart devices and multi-media will, sooner or later, be fully applied to clinical trials. Fundamentally, a clinical trial is a scientific experiment in people. Therefore, the clinical trial data itself are the critical core of the study. Other data (dates, tracking, documentation etc) are important to demonstrate factors such as the integrity of the clinical data, but is effectively supportive. Thus, all clinical trial data should be captured, visualised and analysed live or near live, whether subjects

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are in the clinic, at work or in their homes. This way, a change will be seen in the way clinical trials are conducted as source data will be reduced, simplified or eliminated, and data quality will improve. Costs will fall and some job roles will not be needed or will change and merge. A convergence of clinical trials with the real world of the subject and healthcare setting will occur, and this will accelerate the move towards demonstrating the effectiveness of marketed treatments and outcome-based pricing.



David Connelly is principal founder and Chief Executive Officer at Cmed Group. He has over 25 years' experience in the pharma and CRO industry in areas, including clinical trial design, operations, monitoring, biostatistics and data management. David also has extensive experience in working with top pharma company executives in process re-engineering, performance and change management, design and deployment of new technology. He has a PhD in pharmacology and has lived and worked in the UK, Switzerland and the US.