BioSpectrum the business of Bio & Health Sciences

“Increase in DCT adoption has inevitably brought about regulatory considerations to ensure patient safety and secure data sharing”

01 May 2023 | Interviews | By Hithaishi C Bhaskar

Streamlining laboratory processes accelerates the development of therapies. Digitalisation is transforming the execution practices of biopharmacology and clinical research. In an age of digital innovation, researchers can simplify clinical trials and research and development by integrating lab data, resources, and processes into unified environments. Adopting Decentralised Clinical Trials (DCT) models can improve research outcomes, and productivity, with better compliance. Stakeholders (drug, vaccine, and medical device developers) and CROs must redefine end-to-end approaches to increase the efficiency, security, and accessibility of clinical trials. Digitalised clinical trials and R&D practices in pharmacovigilance can address operational constraints and development challenges. In an interaction with BioSpectrum, Jerome Armellini, Asia Head of Clinical Development & Operations Strategy and R&D Solutions (Asia) at IQVIA, Asia Pacific delves deeper into the decentralised drug discovery landscape.

How do you define the essentials of a decentralised approach in the current drug discovery landscape?

It is essential that such an approach is considered as early as the study design stage. Indeed, successfully executing DCTs is about more than selecting a technology platform or digital components. Every study will require a different combination of technologies, support services, and training to optimise results. This process is based on a thorough review of the targeted patient population, the trials' inclusion/exclusion criteria, duration, patient expectations, protocols, endpoints, and other study requirements.

Decentralised trials leverage technology, including connected devices, and specialised services to engage participants in the community and facilitate patient-centric care through remote pre-screening, tele-visits, at-home treatment and the increasing role of mobile research nurses and staff.

While catering to a fast-moving drug discovery landscape, a decentralised approach aims to bring the patient voice to the trial, reduce the burden on sites and patients, and increase trial awareness, diversity inclusion as well as reach to patients living further away from sites by expanding traditional site boundaries to deliver a more personalised trial experience.

Finally, to ensure a successful decentralised trial, it is also essential for trial sponsors to address the unique concerns and motivations among different populations and demographics to effectively translate patients' interest to trial participation, through the help of an end-to-end digital patient journey solution.

How well are emerging biotechs and biopharmas leveraging digitalisation?

Emerging biotechs and biopharmas (EBPs) have been increasingly leveraging digitalisation throughout the drug discovery process, from drug development strategies to decentralised trials.

In designing more efficient and effective clinical trials, EBPs are increasingly using Artificial Intelligence (AI) and Machine Learning (ML) to leverage multi-omic data and algorithms that are based on historical clinical trials, real-world data and molecular data, to observe the responses of digital patients and improve trial outcomes. AI/ML can also be used to hone the clinical development plan by tailoring the trial to a specific population as algorithms can predict and gauge the trial's effectiveness in the subpopulation and proposed indication.

Overall, EBPs are leveraging digitalisation to drive innovation and improve patient outcomes, both globally and in APAC. However, the extent of digitalisation varies across regions and countries, depending on factors such as a regulatory environment, infrastructure and many others. In their journey towards digitalisation, EBPs sometimes face challenges such as regulatory limitations and getting the right stakeholder support. However, with the help of an experienced CRO, they can successfully leverage digitisation by ensuring that stakeholders understand the benefits of digital adoption through education, training and support, and monitor regulatory developments closely.

How do you describe the development and operational aspect of DCTs in the Japan and Asia Pacific region?

The adoption of DCTs has rapidly soared in the last three years due to the rush to conduct clinical trials during and after the pandemic, and the increased competition among biotech companies. Additionally, the highest quarterly utilisation of decentralised methods shown in Q4 2022 suggests that the industry continues to push into new territory with this set of innovations.

In Asia Pacific, the increase in DCT adoption has inevitably brought about regulatory considerations to ensure patient safety and secure data sharing between patients and investigators. China has imposed strict data privacy laws for the use of AI/ML when targeting and engaging patients, such as the Personal Information Protection Law (PIPL) and Personal Data Security Specification (PDSS). EBPs and biotech companies in the Asia Pacific need to examine regulations in the areas of data privacy, data residency, and data stewardship before embarking on digital adoption.

Several regulators in the Asia Pacific and in the rest of the world, are also developing recommendations for sponsors on DCT deployment (such as, but not limited to, the EMA Recommendation Paper On Decentralised Elements published in December 2022). In Japan, the Pharmaceuticals and Medical Devices Agency is planning to provide DCT guidelines. With this, DCT adoption in Japan will increase.

It is therefore helpful to engage a CRO that knows the best practices across different countries and has the global regulatory landscape understanding, operations support and technology to support digital activities of sites, patients, and sponsors, to accelerate digital adoption in the region.

What should clinical and biopharma operations consider when adopting DCTs? How do companies weigh elements at risk?

Clinical and biopharma operations can consider these aspects when adopting DCTs. First, the trial endpoints must be measurable through a DCT approach and appropriate trial support tools can be adopted based on the clinical trial phase. Second, the regulatory environment in chosen countries must support the required DCT elements such as tele- or home visits, direct-to-patient investigational medicinal product (IMP) shipment, etc. Third, operations must ensure a convenient end-to-end patient experience throughout the DCT process. Decentralised trials are more than just a technology, there is still the need to include a strong human touch to support patients and sites.

Companies can weigh all those critical elements by finding a partner with the expertise to run such trials globally and understand the local compliance and restrictions. Sponsors that partner with mature providers, for a managed service or full-service, will benefit from a successful DCT experience. An experienced partner that is very familiar with the General Data Protection Regulation (GDPR) and data privacy laws, will have the resources to support the needed compliance.

How do you summarise the benefits of adopting DCTs? What is the current status of DCTs in the APAC region?

A key benefit of DCTs is the patient-centricity of the trial design. DCTs provide a convenient end-to-end patient experience that reduces the patient burden, e.g., cutting down travel times and costs, and improving patient engagement and satisfaction. This leads to new patient access, compliance and retention, faster enrolment and trial completion with measurable benefits for sponsors. Many EBPs who develop medicines for rare diseases are also able to enrol patients that would not have participated in a study under the traditional model.

DCTs can also decrease site burden by using a technology platform that acts as a better engagement channel and allows EBPs to gain access to real-time patient progress on demand. A whitepaper that compared DCTs to traditional study models showed that DCTs delivered time and cost efficiencies at virtually every point in the clinical research journey. However, there will always be a role for in-person trials as some patients feel more comfortable being examined by a clinician. Hybrid models, a mix of face-to-face interactions and technology access, are now a permanent fixture of the clinical trial landscape.

The adoption of DCTs is gaining momentum in APAC, such as, but not limited to Australia, China, South Korea, Taiwan, Japan and Malaysia, with many countries starting to implement or develop regulations and/or guidelines for these trials.

Hithaishi C Bhaskar

hithaishi.cb@mmactiv.com