BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

# APAC sponsors/CROs inclination to innovative and optimized DCT model trial designs

05 August 2021 | Opinion | By Hithaishi C Bhaksar

**In conversation with Edwin Ng, Senior Vice President, APAC, Medidata Solutions**

Clinical trials in a drug development process often face multiple hurdles around patient recruitment and management resulting in increased investment, delays, and uncertainties at trial intervals. The high cost of clinical development is a burden on the budget and is inadequate to support on-site operations, leaving potential medicines stuck in the pipeline. To overcome the operational challenges at clinical trials, sponsors and Clinical Research Organisations (CROs) lean towards technology empowering advanced remote monitoring.

The pandemic situation is however drastically convincing sponsor/CROs to appreciate hybrid and technologically advanced remote monitoring approaches through Decentralisation of clinical trials (DTC). As an alternative to a site-anchored, inflexible system, clinical trial designs are adopting novel approaches to reduce patient drop-out rates, increase study effectiveness, save billions to sponsors and ultimately accelerate the drug development process. Current Decentralised trials are wide spectrum operations with eConsent, electronic patient-reported outcomes (ePRO), offering flexible patient-centric choices in a data-protected ecosystem for a comprehensive clinical research solution.

Medidata, the first company in the world to unify direct patient data capture technology redefining end-to-end decentralization for sponsors and CROs. A Dassault Systèmes company, Medidata, announced the Decentralized Clinical Trials (DCT) Program, a comprehensive set of unified, secure technologies that enable complete decentralization across the clinical trial continuum. Headquartered in New York City, Medidata has locations in China, Japan, Singapore, South Korea, the United Kingdom, and the United States. Medidata DCT technologies equip drug, vaccine, and medical device developers (sponsors) and CROs with a platform that leverages technology for workflows virtualization, trial oversight tools, patient safety reports, data quality checks, including facilitation of home delivery of trial drugs.

BioSpectrum Asia brings more insights on the recent surge in decentralized clinical trials in the APAC region while conversing with ***Edwin Ng, Senior Vice President at Medidata Solutions***.

**How do you describe the economic and operational benefits of adopting a DCT unified platform to minimize data discrepancies, transfer lags, security concerns, and trial disruption risk?**

Sponsors and CROs are turning to decentralized trial models in an effort to bring increased efficiency, security, and accessibility to the clinical research process. The Medidata DCT Program revolutionizes sponsor study oversight by supporting sponsors and CROs easy adoption of risk-based approaches to study execution, rather than historically reactionary and inefficient on-site practices. The potential benefits of a DCT model range from reduced patient and sponsor burden, to increased accrual and retention of a more diverse trial population. In this way, the entire clinical trial life cycle is improved due to efficiencies at each step of the process. With continual digital oversight with our platform, sponsors and CROs can continually monitor patient safety and data quality, without waiting weeks or months for an on-site visit. DCTs have the potential to change the entire clinical trial process as we know it today.

Medidata DCT Program is the only unified platform that enables full, end-to-end clinical trial decentralisation — all on Medidata Clinical Cloud. This means sponsors and CROs do not need to integrate multiple vendors or solutions. Data is shared natively across products, allowing sponsors and CROs to decentralise as much or as little of the trial process as they choose, without worrying about compromising data integrity. The result is a more efficient, more secure route to decentralization that only Medidata can provide.

**How is Medidata redefining end-to-end decentralization standards for sponsors (drug, vaccine, and medical device developers) and CROs?**

To be successful, DCTs cannot just be about patient participation. Medidata is redefining how sponsors and CROs manage their activities not just at the site but off the site as well, giving them the flexibility to support any level of decentralization required in a protocol.

The Medidata DCT Program's embedded capabilities for risk identification, monitoring, and mitigation allow for true digital oversight, where physical and virtual interactions with sites can be optimized while maintaining patient safety and data quality. The program also allows for powerful workflows driven from patient-centric data, such as shipping the investigational product directly to the patient or making automated dosage adjustments.

Medidata Digital Oversight enables continuous data monitoring from anywhere, allowing sponsors and CROs to innovate and optimize approaches to trial design, physical and virtual interactions with sites, and support a holistic portfolio strategy. Because patient data collection does not happen in a typical controlled environment, DCT models have inherent data quality risks, and when point solutions are cobbled together instead of using a unified platform, there's an additional layer of risk involved. Which is why the Medidata DCT Program being fully integrated and hosted on a unified platform is so significant.

Technology needs to be integrated into the operational and decision-making processes. Interoperability is critical. We can put all these capabilities to DCT the entire trial on one data platform and tune them up or down based on the specific customer protocol design. With these flexibilities, Medidata is able to support sponsors and CROs in research areas ranging from cardiovascular disease, neurology and oncology, to rare diseases and infectious diseases such as Covid-19.

**How do you foresee major DCT markets for Medidata in the APAC region and its edge over the other players in the market?**

The DCT Program marks an important evolution in Medidata's vision for how we can better serve patients and customers, by accelerating research and bringing novel therapies to market in record time. With APAC fast becoming the preferred choice for clinical trials, it is crucial that we provide the area with cutting-edge tools. We want to ensure that sponsors and CROs in APAC have access to the leading end-to-end, unified and secure life sciences platform.

Globally, Medidata has more than 90 accredited partners with 24,000 studies conducted. Of these 7,700 of these studies are in APAC. We recognize APAC's great growth potential. Several sponsors in Korea and China are using our solutions, such as eConsent and eCoA in advanced clinical trials. To ensure the growth of the region, we are also aggressively expanding our team in the region to better support our partners and customers in their trial studies.

**How does Medidata plan to leverage the DCT Program to accelerate research in the APAC region and bring novel therapies to market in record time?**

At the industry level, there is a struggle to efficiently manage clinical trials due to a fragmented and rapidly changing trial ecosystem. As a result, clinical operations, in APAC or any other part of the world, must evolve at the pace of the research it supports. There are three key areas where clinical operations must evolve to meet the needs of today's complex trials. The first is trial execution. Optimized trial operations require effective communication and information sharing. Traditional clinical operations practices require data entry within multiple siloed locations, which creates a high risk that key activities and actions will be missed.

The second is the ability to evolve the strategy for clinical operations towards risk-based approaches using risk-based quality management (RBQM) principles. While it's clear from recent regulatory guidance and learnings from the pandemic that companies who adopted risk-based approaches towards study design and execution fared better during COVID-19, most RBQM technologies are essentially cobbled together point solutions, rather than holistic end-to-end solutions.

Finally, we know that future trials will not look or perform the same as they have in the past. Today's technologies must be able to support all manner of brick and mortar as well as decentralized trials. At the intersection of these areas is digital oversight, Medidata's unique set of capabilities to drive the next generation of clinical operations.

**Hithaishi C Bhaskar**

hithaishi.cb@mmactiv.com