

Medidata extends a secure platform for Decentralization of Clinical Trials (DCT)

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The first company in the world to unify direct patient data capture technology with study oversight and monitoring, Medidata redefines end-to-end decentralization for sponsors and CROs



Medidata, a Dassault Systèmes company, announced the launch of the <u>Medidata Decentralized Clinical Trials (DCT) Program</u>, the most comprehensive set of unified, secure technologies that enable full 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.

For the first time ever, drug, vaccine, and medical device developers (sponsors) and contract research organizations (CROs) can take advantage of the only platform offering on the market which combines:

- Technology and workflows to virtualize patient participation
- · Tools that facilitate sponsor oversight of patient safety and data quality
- Direct-to-patient services, including facilitation of delivery of study drugs to the home

The Medidata DCT Program captures participant data remotely from anywhere, at any time. It aggregates and transforms that data, monitors the data to identify quality issues to mitigate risk and ensure patient safety, and runs powerful analytics to draw new insights leading to better outcomes for patients, researchers, sites, sponsors, and CROs.

Through a range of capabilities on a common platform that can be individually turned "on" or "off" in various combinations using the <u>Trial Dial</u>[™] concept, the Medidata DCT Program provides the highest level of customization of decentralizing solutions based on study protocol design. This allows study sponsors to adjust and choose everything from traditional onsite trials, to fully decentralized models, and every hybrid trial design in between.

The Medidata DCT Program revolutionizes the paradigm of sponsor study oversight by supporting sponsors and CROs to easily adopt risk-based approaches to study execution, rather than historically reactionary and inefficient on-site practices. Embedded capabilities for risk identification, monitoring, and mitigation allow for truly digital oversight, where physical and virtual interaction with sites can be optimized while maintaining patient safety and data quality. The Medidata DCT Program

also allows for powerful workflows driven from patient-centric data, such as shipping the investigational product directly to the patient and automated dosage adjustments.