Medidata Becomes First Company to Offer End-to-End, Unified, Secure Platform for Decentralization of Clinical Trials (DCT)

- 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
- The unique Medidata Trial Dial™ concept provides the industry's highest level of customization for clinical trial decentralization - enabling fully decentralized or hybrid studies

New York, New York – June 15, 2021 – Medidata, a Dassault Systèmes company, today announced the launch of the Medidata Decentralized Clinical Trials (DCT) Program, the most comprehensive set of unified, secure technologies that enable full decentralization across the clinical trial continuum. 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.

"The life science industry has seen accelerating interest and adoption of decentralized trial technology in the wake of the COVID-19 pandemic," said Anthony Costello, president, patient cloud at Medidata. "Sponsors and CROs are increasingly turning to decentralized trial models in an effort to bring increased efficiency, security, and accessibility to the clinical research process."

Through a range of capabilities on a common platform that can be individually turned "on" or "off" in various combinations using the Trial Dial™ 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 investigational product directly to the patient and automated dosage adjustments.

“We are very proud to say that, as a trusted partner to the life science sector for more than 20 years, Medidata is now the only company providing a full suite of virtual capabilities to enable complete trial decentralization, encompassing both patient and site interactions,” added Costello. “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.”

To date, Medidata has applied its decentralizing technologies across more than 44,000 clinical sites around the world in multiple languages involving more than 600,000 patients with a wide array of illnesses. Nearly 350 sponsors and CROs have trusted Medidata to handle the increasing speed and volume of electronically sourced patient data generated by modern trials. The single platform minimizes the opportunity for data discrepancies and transfer lags, which can lead to security concerns and increased risk of trial disruption.

According to Gartner, a leading research and advisory company, “Life science CIOs advancing healthcare and life science digital optimization and modernization should… establish a technology strategy by prioritizing digital trial solutions that combine wearables, mobile apps, IoT and advanced data analytics. This will enable a truly patient-centric and decentralized approach to clinical research.”[1]

The COVID-19 crisis emphasized the pivotal role of technology in accelerating safe clinical trial development. In fact, Medidata technology helped to bring a COVID-19 vaccine through the full clinical trial life cycle in under a year. For this effort, the vaccine developer used a suite of Medidata technologies, including Rave EDC (electronic data capture); eCOA (electronic clinical outcomes assessment), and Detect (centralized statistical monitoring)—these tools allowed study teams to course-correct before trial quality and timing were affected by potential risks.

Regulatory agencies around the world have begun embracing remote technology solutions, especially remote monitoring, electronic informed consent (eConsent), telemedicine, and direct shipment of investigational products to patients. Specifically, the United States Food & Drug Administration (FDA) is expected to issue a draft guidance regarding decentralized clinical trials this year, with special emphasis on endpoint analysis, data quality and control, and the appropriate use of eConsent. As a pioneer in decentralizing the clinical trial process, Medidata is primed to support the industry in the adoption and best use of these innovative new technologies.

Medidata is a wholly owned subsidiary of Dassault Systèmes, which with its 3DEXPERIENCE platform is positioned to lead the digital transformation of life sciences in the age of personalized medicine with the first end-to-end scientific and business platform, from research to commercialization.

1. Gartner, Life Science CIOs: Map Your Pathway to Digital Trials, Jeff Smith, 18 August, 2020.

About Medidata
Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,700+ customers and partners access the world's most-used platform for clinical development, commercial, and real-world data. Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at www.medidata.com and follow us @Medidata.

About Dassault Systèmes
Dassault Systèmes, the 3DEXPERIENCE Company, is a catalyst for human progress. We provide business and people with collaborative 3D virtual environments to imagine sustainable innovations. By creating virtual twin experiences of the real world with our 3DEXPERIENCE platform and applications, our customers push the boundaries of innovation, learning and production. Dassault Systèmes brings value to more than 290,000 customers of all sizes, in all industries, in more than 140 countries. For more information, visit www.3ds.com.

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