Medidata, TriNetX, and Datavant Partner to Enable Seamless Integration of Real-World Data in Clinical Development

Enables compliant, timely surveillance and outcomes research to help get safe and effective therapies to patients faster

New York, Cambridge, San Francisco -- (October 29, 2020) -- Medidata, a Dassault Systèmes company, TriNetX, and Datavant announced a partnership that will accelerate the use of real-world data (RWD) to power clinical research. Linking RWD, which are data not collected during the specific context of the trial, can help improve understanding of the long-term safety and efficacy of new therapies. This partnership will enable users of Medidata's end-to-end clinical research platform to securely link their clinical data with patient consent to de-identified patient data without unblinding the study. The solution leverages Datavant's Patient Key technology and data ecosystem, as well as RWD from TriNetX's global network of healthcare organizations who participate in this program.

Pooling and integrating disparate datasets to form a complete picture of the patient experience can create insights to inform decision-making across the product life cycle, from R&D to pre-launch to post-launch. Real world treatment patterns are also used to inform novel therapy development and adoption. Pooled clinical trial data is increasingly being used to design

synthetic control arms, and even to power algorithms that can predict things like patient drop out.

“Medidata’s mission is to enable the life sciences industry to generate the evidence and insights it needs to power clinical development and get safe and effective therapies to patients faster,” said Arnaub Chatterjee, senior vice president of Product at Acorn AI by Medidata. “This partnership fulfills the mission of creating a unified data feedback loop between the clinical trial and the real world and expands the possibilities for analytics conducted during and after clinical trials while keeping the clinical study blinded.”

The Medidata, TriNetX, and Datavant partnership will enable use of RWD throughout all phases of clinical development:

- For new therapies where trials have not yet begun: Clinical trial sponsors can better validate the patients enrolling in their trial
- During trials: Sponsors can enhance safety monitoring, build external control arms, and enrich and accelerate understanding of their patients via hybrid studies, where traditional randomized controlled clinical studies add pragmatic RWD collection
- After the completion of a trial: Drug safety and efficacy of their drugs in the trial cohort (preserving the randomization of the trial design) can be tracked easily without manual patient follow up; sponsors can also generate a data feedback loop to better design future trials

“Our global health research network is focused on bringing the power of real-world data to speed the trial design and site selection process for the benefit of sponsors and patients,” said Maulik Mehta, Chief Business Officer at TriNetX. “This partnership extends our research solution’s ability to power the trial analysis and long-term surveillance needs of our life sciences clients with our real-world data assets and expertise.”

RWD linkage will be particularly valuable for the clinical trials conducted for COVID-19 to support the collection of additional safety and surveillance data. Patients enrolled in a clinical trial utilizing Medidata’s solutions will have the option to grant consent for their data to be linkable using Datavant’s de-identified Patient Keys to both TriNetX’s broad RWD assets and Datavant’s open data ecosystem. This enables sponsors to cost-effectively study the efficacy and safety of their therapies for many years after the completion of the trial with less risk of losing patients to follow-up.

“As the COVID-19 pandemic has demonstrated, the value of real-world data to speed clinical development and understand new potential therapies has never been greater,” said Travis May, Chief Executive Officer of Datavant. “We are thrilled that our technology will support industry leaders Medidata and TriNetX to enable sponsors to connect real-world data for novel analytics while protecting patient privacy. As new vaccines and treatments come to market faster than ever before, the use of real-world data to gather additional safety and efficacy data will be critical to ensuring patient safety and continued evidence gathering.”

The clinical trial and real-world data ecosystems are complex, and enabling the incorporation of real-world data at scale will require cooperation among a large number of players across the industry including sponsors, contract research organizations, technology platforms, data originators and aggregators, and analytics companies. In order to enable the connection of clinical trial data and real-world data, Medidata, TriNetX and Datavant are pursuing an open, partnership-first approach and look forward to continued collaboration across the industry to modernize the clinical trial infrastructure for patient benefit.

About Datavant
Datavant's mission is to connect the world's health data to improve patient outcomes. Datavant works to reduce the friction of data sharing across the healthcare industry by building technology that protects the privacy of patients while supporting the linkage of de-identified patient records across datasets. Datavant is headquartered in San Francisco. Learn more about Datavant at www.datavant.com.

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 1,600+ 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, The Operating System for Life Sciences™.

About TriNetX
TriNetX is the global health research network that connects the world of drug discovery and development from pharmaceutical company to study site, and investigator to patient by sharing real-world data to make clinical and observational research easier and more efficient. TriNetX combines real time access to longitudinal clinical data with state-of-the-art analytics to optimize protocol design and feasibility, site selection, patient recruitment, and enable discoveries through the generation of real-world evidence. The TriNetX platform is HIPAA and GDPR compliant. For more information, visit TriNetX at www.trinetx.com or follow @TriNetX on Twitter.

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